



National Health and Nutrition Examination Survey (NHANES)

Cardiovascular Fitness Procedures Manual



January 2005

TABLE OF CONTENTS

<u>Chapter</u>		<u>Page</u>
1	OVERVIEW OF CARDIOVASCULAR FITNESS.....	1-1
	1.1 Cardiovascular Fitness in NHANES.....	1-1
	1.2 Personnel.....	1-2
	1.3 Integrated Survey Information System (ISIS)	1-2
2	EQUIPMENT/SUPPLIES/MATERIALS	2-1
	2.1 Quinton MedTrack ST65 Treadmill with Hyperdrive	2-1
	2.1.1 Maintenance of the Treadmill	2-2
	2.1.2 Calibration of the Treadmill.....	2-5
	2.2 Quinton MedTrack ST Programmable Controller	2-6
	2.2.1 Maintenance of the Programmable Controller	2-8
	2.2.2 Calibration of the Programmable Controller.....	2-8
	2.3 Colin STBP-780 Automatic Blood Pressure Monitor	2-10
	2.3.1 Maintenance of the Automatic Blood Pressure Monitor.....	2-11
	2.3.2 Calibration of the Automatic Blood Pressure Monitor	2-12
	2.3.3 Mercury Manometer (Used for Calibration)	2-14
	2.3.4 Mercury Spills and Leaks.....	2-15
	2.4 SECA Floor Scale Model 815	2-16
	2.4.1 Maintenance and Calibration of the Floor Scales	2-17
	2.5 SECA Portable Stadiometer Model 222	2-18
	2.5.1 Maintenance and Calibration of the Stadiometer	2-18
	2.6 Description of Supplies.....	2-19
	2.6.1 ECG Electrodes/Alcohol Prep Pads/Abrasive Pads	2-19
	2.6.2 Running Shoes	2-19
	2.6.3 Mesh Vests.....	2-19
	2.7 Repair of Equipment.....	2-20
	2.8 Equipment Manuals	2-20

TABLE OF CONTENTS (continued)

<u>Chapter</u>		<u>Page</u>
	2.9 Troubleshooting.....	2-21
	2.9.1 Quinton MedTrack ST 65 Treadmill and Controller.....	2-21
	2.9.2 Colin STBP-780 Blood Pressure Monitor.....	2-22
3	PROTOCOL	3-1
	3.1 Exclusions to the CV Fitness Component	3-1
	3.1.1 Shared Exclusion Questions.....	3-1
	3.1.2 Medical History.....	3-2
	3.1.3 Medications.....	3-3
	3.1.4 Be All Question.....	3-4
	3.1.5 Exclusions Based on Heart Rate and Blood Pressure	3-5
	3.2 Introduction to Component.....	3-5
	3.3 Measurement of Height and Weight to Determine Body Mass Index	3-6
	3.3.1 Height.....	3-7
	3.3.2 Weight.....	3-7
	3.4 Checking SP's Footwear.....	3-9
	3.5 Determination of Physical Activity Readiness Code.....	3-10
	3.5.1 Questions to Determine PAR Code: English Version.....	3-10
	3.5.2 Questions to Determine PAR Code: Spanish Version	3-13
	3.6 Determination of Predicted VO2 Max.....	3-14
	3.7 Determination of Exercise Protocol.....	3-15
	3.8 Preparation for Treadmill Test.....	3-15
	3.8.1 Preparation of Skin and Placement of Electrodes	3-16
	3.8.2 Selection of Arm for Blood Pressure Monitoring	3-17
	3.8.3 Selection of Cuff Size and Placement of Cuff	3-18
	3.8.4 Room Temperature.....	3-18
	3.8.5 Mesh Vest	3-19
	3.9 Treadmill Test.....	3-19
	3.9.1 Setup of Colin STBP Automatic BP Monitor	3-19

TABLE OF CONTENTS (continued)

<u>Chapter</u>		<u>Page</u>
	3.9.2 Setup of Programmable Controller and Treadmill	3-20
	3.9.3 Obtaining Pretest Blood Pressure and Heart Rate	3-21
	3.9.4 Script for Explaining Treadmill Test	3-22
	3.9.5 Demonstrating How to Walk on a Treadmill	3-23
	3.9.6 Warm-up (00:00 - 02:00 Minutes)	3-24
	3.9.7 RPE Explanation and Assessment	3-24
	3.9.8 Stage 1 (00:00 - 03:00 Minutes)	3-26
	3.9.9 Stage 2 (00:00 - 03:00 Minutes)	3-27
	3.9.10 Recovery Stages 1, 2, & 3 (If Necessary)	3-29
	3.9.11 End of Test	3-30
3.10	Procedure if Values Exceed Criteria	3-30
	3.10.1 Exception for RPE Greater Than 17 at End of Stage 2	3-31
3.11	Procedure if SP is Unable to Adhere to the Protocol	3-32
3.12	Procedure to Change Predicted Exercise Protocol	3-32
	3.12.1 Increasing the Exercise Protocol	3-34
	3.12.2 Decreasing the Exercise Protocol	3-35
	3.12.3 Changing Exercise Protocol During Warm-up	3-35
	3.12.4 Monitoring the Heart Rate During Stage 1	3-37
	3.12.5 Monitoring the Heart Rate during Stage 2	3-38
3.13	Procedure to Stop Treadmill Test Early	3-39
	3.13.1 Priority 1 Stopping Criteria	3-39
	3.13.2 Priority 2 Stopping Criteria	3-41
3.14	Procedure to Recover/Restart an Exam	3-42
3.15	Recording Problems with Data Acquisition During the Treadmill Test	3-43
3.16	Component Status	3-43
4	INTEGRATED SURVEY INFORMATION SYSTEM (ISIS) DATA ENTRY SCREENS	4-1
4.1	Shared Exclusion Questions	4-1
4.2	Height and Weight Measurements to Determine BMI	4-3
	4.2.1 Edits on Data Entry for Weight and Height	4-5

TABLE OF CONTENTS (continued)

<u>Chapter</u>		<u>Page</u>
4.3	Questions to Determine Exercise Protocol (PAR Code Questions) ...	4-10
4.3.1	First Level Questions	4-12
4.3.2	Second Level Questions (Little or No Regular Physical Activity)	4-13
4.3.3	Second Level Questions (Regular Modest Physical Activity)	4-14
4.3.4	Second Level Questions (Regular Heavy Physical Activity)	4-16
4.3.5	Required Data Entry for PAR Questions	4-18
4.4	Pretest Measurements	4-19
4.4.1	Digital Thermometer for Measuring Room Temperature ...	4-20
4.4.2	Exam Preparation –Arm Used, Cuff Size, Mesh Vest Used	4-21
4.4.3	Capturing Blood Pressure Measurements	4-27
4.4.4	Demonstrating and Explaining How to Walk on a Treadmill	4-28
4.4.5	Required Data Entry for Arm and Cuff Size.....	4-29
4.4.6	Required Data Entry for BP Measurements.....	4-30
4.5	Treadmill Test.....	4-31
4.5.1	Function of Treadmill Test Screen.....	4-31
4.5.2	Preparing the Treadmill and Controller	4-34
4.5.3	Getting the SP on the Treadmill.....	4-35
4.5.4	Warm-up	4-36
4.5.5	Show Data	4-39
4.5.6	Stage 1	4-40
4.5.7	Stage 2.....	4-49
4.5.8	Recovery Stages.....	4-52
4.5.9	Checking Estimated VO2 Max	4-53
4.5.10	Component Status for Routine Test	4-54
4.6	Changing the Exercise Protocol.....	4-55
4.6.1	Changing the Treadmill Controller	4-55
4.6.2	Decreasing the Exercise Protocol.....	4-56
4.6.3	Increasing the Exercise Protocol.....	4-58
4.6.4	Lowest and Highest Protocol	4-60
4.7	Emergency Stop.....	4-63
4.8	Priority 1 Stopping Criteria.....	4-64

TABLE OF CONTENTS (continued)

<u>Chapter</u>		<u>Page</u>
4.9	Early Termination of Test – Go to Recovery.....	4-67
4.9.1	Data Not Within Acceptable Limits.....	4-68
4.10	Priority 2 Stopping Criteria.....	4-77
4.11	Combination of Priority 1 & 2 Stopping Criteria	4-80
4.12	Problems With Data Acquisition During Treadmill Test	4-81
4.13	Component Status Categories.....	4-84
4.13.1	Complete	4-84
4.13.2	Partial	4-85
4.13.3	Not Done.....	4-91
5	REFERRALS AND REPORT OF FINDINGS	5-1
5.1	Observation Referrals	5-1
5.2	Report of Findings for CV Fitness.....	5-3
6	QUALITY CONTROL.....	6-1
6.1	Overview.....	6-1
6.2	Training.....	6-1
6.2.1	Initial Training	6-1
6.2.2	Annual Retraining.....	6-2
6.3	Equipment and Room Set-up Checks	6-3
6.3.1	Daily.....	6-3
6.3.2	Weekly	6-4
6.3.3	Stand.....	6-5
6.4	Data Entry Screens for QC on Equipment.....	6-6
6.4.1	Quality Control Reminder Message Box	6-6
6.4.2	Utilities Menu to Select Quality Control.....	6-7
6.4.3	Quality Control Logon Box	6-7
6.4.4	Data Entry Screen for QC Daily Checks.....	6-8
6.4.5	Data Entry Screen for QC Weekly Checks	6-12
6.4.6	Data Entry Screen for QC Start of Stand Checks.....	6-16
6.4.7	Incomplete Entry of Quality Control Data.....	6-18

TABLE OF CONTENTS (continued)

<u>Chapter</u>		<u>Page</u>
6.5	Observational Visits.....	6-18
6.5.1	Technician Competency Evaluation Form.....	6-19
6.5.2	Quality Control Review of CV Fitness exclusions in Physician's Exam.....	6-24
6.5.3	Site Visit Report Form	6-26

List of Appendixes

Appendix

A	SCRIPTS.....	A-1
B	EXCLUSIONS BASED ON MEDICAL CONDITIONS	B-1
C	EXCLUSIONS BASED ON MEDICATIONS	C-1
D	PHYSICAL ACTIVITY READINESS CODE	D-1
E	REVIEW OF EDIT CRITERIA	E-1
F	CALCULATION OF PREDICTED V02 MAX.....	F-1
G	CALCULATION OF ESTIMATED V02 MAX.....	G-1
H	DETERMINATION OF EXERCISE PROTOCOL	H-1
I	REFERENCE RANGES FOR V02 MAX.....	I-1
J	SPEED AND GRADE TABLE BY PROTOCOL AND STAGE.....	J-1
K	SAMPLE DATA ENTRY SCREENS.....	K-1

List of Tables

Table

2-1	Troubleshooting problems with the Quinton Med Track ST65 Treadmill and Controller	2-21
2-2	Troubleshooting problems with the STBP monitor	2-22

TABLE OF CONTENTS (continued)

List of Figures

<u>Figure</u>		<u>Page</u>
2-1	Quinton MedTrack ST65 Treadmill	2-1
2-2	Treadmill calibration.....	2-4
2-3	Calibration of elevation	2-6
2-4	Quinton MedTrack ST Programmable Controller	2-7
2-5	Colin STBP-780 Automatic Blood Pressure Monitor.....	2-11
3-1	Correct body placement for height measurement	3-8
3-2	Site for placement of electrodes (1).....	3-16
3-3	Site for placement of electrodes (2).....	3-18
3-4	Treadmill controller - changing the exercise protocol.....	3-34
5-1	Menu to select observation referral.....	5-1
5-2	Pick list of SP's in current session.....	5-2
5-3	Observation referral in CV Fitness	5-2
5-4	Observation Referral from CV Fitness in physician's referral review box	5-3

List of Exhibits

<u>Exhibit</u>		
3-1	CV Review for Exclusion Medications	3-4
4-1	Shared Exclusions disabled from previous component	4-1
4-2	Blood Pressure Section Status from Physician	4-2
4-3	Weight and height measurements from body composition.....	4-3
4-4	Weight and height measurements in CV Fitness room.....	4-4

TABLE OF CONTENTS (continued)

List of Exhibits (continued)

<u>Exhibit</u>		<u>Page</u>
4-5	Edit message on incorrect data entry for weight.....	4-5
4-6	Edit message on incorrect data entry for weight (below edit range).....	4-6
4-7	Edit message on incorrect data entry for height.....	4-7
4-8	Required data entry for height and weight.....	4-8
4-9	Cannot calculate VO2 max.....	4-8
4-10	Partial status with comment ‘Other, specify’.....	4-9
4-11	Questions to determine protocol.....	4-10
4-12	First level questions to determine exercise protocol.....	4-12
4-13	Little or no regular physical activity (second level questions).....	4-13
4-14	Regular modest physical activity (second level questions).....	4-14
4-15	Second level questions (regular heavy physical activity).....	4-16
4-16	Required data entry for first level activity questions.....	4-18
4-17	Pretest measurements.....	4-19
4-18	Unable to obtain room temperature.....	4-20
4-19	Exam preparation – arm selected.....	4-21
4-20	SP excluded if neither arm can be used for BP measurement.....	4-22
4-21	SP excluded due to physical limitation.....	4-22
4-22	Partial status with physical limitation if CNO selected for arm.....	4-23
4-23	Selection of cuff size.....	4-24
4-24	Problem with cuff size.....	4-25

TABLE OF CONTENTS (continued)

List of Exhibits (continued)

<u>Exhibit</u>		<u>Page</u>
4-25	Mesh vest used.....	4-26
4-26	Blood pressure data capture.....	4-27
4-27	Demonstrate and explain how to walk on a treadmill.....	4-28
4-28	Required data entry for arm and cuff used.....	4-29
4-29	Required data entry for blood pressure.....	4-30
4-30	Treadmill test data entry screen.....	4-31
4-31	Preparing the treadmill and controller.....	4-34
4-32	Starting the timer.....	4-36
4-33	Explaining the rating of perceived exertion (RPE).....	4-37
4-34	Getting RPE for warm-up.....	4-38
4-35	Show data window.....	4-39
4-36	Show data message.....	4-39
4-37	Treadmill test stage 1 – routine test.....	4-40
4-38	Get rating of perceived exertion (RPE).....	4-41
4-39	Compare heart rate on monitor and screen.....	4-42
4-40	Example 1 – manually entered heart rate - not necessary.....	4-43
4-41	Show data screen for Example 1.....	4-44
4-42	Example 2 – manually entered heart rate - necessary.....	4-44
4-43	Show data window for Example 2.....	4-45
4-44	Example 3 - manually entered heart rate - incorrect data entry.....	4-46

TABLE OF CONTENTS (continued)

List of Exhibits (continued)

<u>Exhibit</u>		<u>Page</u>
4-45	Show data window for Example 3	4-47
4-46	Manual entry fields disabled.....	4-48
4-47	Treadmill test stage 2 – (19 through 49 years).....	4-49
4-48	Treadmill test stage 2 – (12 through 18 years).....	4-51
4-49	Treadmill test, recovery – routine test	4-52
4-50	Checking estimated VO2 max	4-53
4-51	VO2 max not calculated	4-53
4-52	Component status - complete.....	4-54
4-53	Treadmill controller	4-55
4-54	Decreasing the exercise protocol	4-56
4-55	Decreased protocol	4-57
4-56	Increasing the exercise protocol.....	4-58
4-57	Changing the protocol in stage 1 or 2 - message	4-59
4-58	Lowest protocol for 19 through 49 years	4-60
4-59	Lowest protocol for 12 through 18 year olds.....	4-61
4-60	Highest protocol for all age groups (12 through 49 years)	4-62
4-61	Emergency stop.....	4-63
4-62	Priority 1 stopping criteria - other.....	4-64
4-63	Priority 1 stopping criteria - required entry	4-66
4-64	Go to recovery	4-67

TABLE OF CONTENTS (continued)

List of Exhibits (continued)

<u>Exhibit</u>		<u>Page</u>
4-65	Heart rate greater than specified criteria Warm-up (12 through 49 years)	4-69
4-66	Heart rate greater than specified criteria Stage 1 (12 through 49 years).....	4-70
4-67	Heart rate greater than specified criteria Stage 2 (12 through 18 years).....	4-71
4-68	Heart rate greater than specified criteria Stage 2 (19 through 49 years).....	4-72
4-69	Heart rate greater than 100 percent during any stage (12 through 49 years)	4-73
4-70	SBP not within acceptable limits	4-74
4-71	DBP not within acceptable limits	4-75
4-72	Rating of perceived exertion not within acceptable limits.....	4-76
4-73	Priority 2 stopping criteria	4-77
4-74	Component status for priority 2	4-78
4-75	SP unable to stop gripping handrails	4-79
4-76	Data entry for combination of Priority 1 & 2 criteria	4-80
4-77	Problems with data acquisition - No problems	4-81
4-78	Problems with data acquisition - BP, data capture, and HR	4-82
4-79	Problems with data acquisition - electrodes, BP cuff, and treadmill controller.	4-83
4-80	Component status - complete.....	4-84
4-81	Component status - partial (1).....	4-85
4-82	Component status - partial (2).....	4-87
4-83	Component status - partial (3).....	4-88
4-84	Component status – partial (4).....	4-89

TABLE OF CONTENTS (continued)

List of Exhibits (continued)

<u>Exhibit</u>		<u>Page</u>
4-85	Component status - partial - required comments	4-90
4-86	Component status - not done.....	4-91
5-1	Menu to select observation referral.....	5-1
5-2	Pick list of SPs in current session	5-2
5-3	Observation referral in CV Fitness	5-2
5-4	Observation referral from CV Fitness in physician’s referral review box.....	5-3
6-1	Quality control reminder message box	6-6
6-2	Utilities menu to select quality control	6-6
6-3	Quality control logon.....	6-7
6-4	Quality control daily checks (1).....	6-8
6-5	Quality control daily checks (2).....	6-9
6-6	Quality control daily checks (3).....	6-10
6-7	Quality control daily checks (4).....	6-11
6-8	Quality control weekly checks (1)	6-12
6-9	Quality control weekly checks (2)	6-13
6-10	Quality control weekly checks (3)	6-14
6-11	Quality control weekly checks (4)	6-15
6-12	Quality control ‘start of stand’ checks (1)	6-16
6-13	Quality control ‘start of stand’ checks (2)	6-16
6-14	Quality control ‘start of stand’ checks (3)	6-17

TABLE OF CONTENTS (continued)

List of Exhibits (continued)

<u>Exhibit</u>		<u>Page</u>
6-15	Quality control incomplete entry	6-18
6-16	Technician Competency Evaluation Form	6-20
6-17	Checklist for medication review	6-24
6-18	Checklist for CV Fitness exclusion questions	6-25
6-19	Site Visit Report form.....	6-26

1. OVERVIEW OF CARDIOVASCULAR FITNESS

1.1 Cardiovascular Fitness in the National Health and Nutrition Examination Survey (NHANES)

Cardiovascular disease is currently the leading cause of death in the United States for both men and women. A sedentary lifestyle (along with elevated blood cholesterol levels, hypertension, and smoking) is a major modifiable risk factor for cardiovascular disease. According to current data however, only about 24 percent of American adults currently meet the physical activity recommendations outlined in the 1996 Surgeon General's Report.

In previous versions of NHANES, no direct cardiovascular fitness assessment components have been included in the data collection. A cardiovascular fitness component will be included with the current NHANES.

Cardiovascular fitness is defined as the body's ability to uptake, transport, and utilize oxygen. Other terminology that is sometimes used to describe cardiovascular fitness includes VO_2 max, maximal oxygen uptake, maximal oxygen consumption, and aerobic power.

A maximal treadmill test is considered to be the most valid method of measuring cardiovascular fitness. By collecting and analyzing expired air during the test, one can directly measure VO_2 max. This type of testing is done in a clinical setting and is extremely expensive and time consuming. A 12-lead electrocardiogram (ECG) is typically utilized during a maximal test. Thus, maximal treadmill testing can be used to diagnose stress induced cardiac arrhythmias and coronary heart disease. Due to time constraints, test setting, expense, and the large number of SPs in NHANES, it is neither feasible nor possible to utilize this method to evaluate cardiovascular fitness.

Submaximal treadmill testing will be utilized as a means to estimate cardiovascular fitness levels during NHANES. Based on variables including gender, age, BMI, and self-reported level of physical activity, SPs will be assigned to one of eight treadmill test protocols, each varying in difficulty. Each of the eight protocols was designed so that the SP could walk at all times. The goal of each protocol is to elicit a heart rate that is approximately 75 percent of the predicted maximum ($220 - \text{age}$) by the end of the test. Each protocol includes a 2-minute warm-up, followed by two 3-minute stages and a 2-minute

cool-down period. By monitoring heart rate response to each of the 3-minute stages, VO₂ max can be predicted with a reasonable degree of accuracy. It is important to note that while the heart rate will be monitored during the treadmill test, there will be no electrocardiogram (ECG) on the screen. Therefore, the NHANES submaximal treadmill test is intended only to estimate cardiovascular fitness levels. It cannot be used to diagnose or identify any cardiovascular disease.

SPs will be carefully screened prior to the treadmill test using questionnaires and measurements of resting heart rate and resting blood pressure. High risk (symptomatic, with disease, etc.) individuals will be excluded, so that only apparently healthy individuals will undergo treadmill testing. The combination of screening, monitoring, and the submaximal nature of the test will all contribute to the safety of this component.

1.2 Personnel

Maximizing safety and obtaining meaningful data are the two primary goals of the technologist with regard to the submaximal treadmill test. The demeanor of the treadmill technologist should be one of relaxed confidence so as to immediately put the SP at ease. Although there are time constraints to be aware of, treadmill testing procedures should not be rushed, and all procedures must be clearly explained prior to initiating the process. Technologists are expected to pay close attention to the data and the SP at all times, and also be sensitive to the confidentiality of the data. Knowledge of normal vs. abnormal responses to exercise is essential, as well as knowing when a test should be terminated early. Since the submaximal treadmill test is a fitness test (not a diagnostic test), and since technologists are not licensed physicians, no diagnoses will be attempted or made by technologists at any time. Although submaximal treadmill testing is very safe, all technologists must be CPR certified.

1.3 Integrated Survey Information System (ISIS)

The Integrated Survey Information System (ISIS) is a computer-based infrastructure designed to support all survey operations including sample management, data collection, data editing, quality control, analysis, and delivery of NHANES data. Each component in NHANES such as Cardiovascular (CV) Fitness has a computer application for direct data entry. Data collected in the CV Fitness room of the mobile examination center is directly entered in the ISIS system computers. In

addition, data from biomedical equipment such as the blood pressure monitor in CV Fitness is directly downloaded to the ISIS system where it is displayed on the computer screen and stored in the system database. For more information about the NHANES and the ISIS system, see the *ISIS User Guide* and Presentations/ISIS Overview Presentation on the IntraWeb.

2. EQUIPMENT/SUPPLIES/MATERIALS

Below you will find descriptions of the equipment necessary to complete the Cardiovascular Fitness component of the National Health and Nutrition Examination Survey (NHANES).

2.1 **Quinton MedTrack ST65 Treadmill with Hyperdrive**

The Quinton MedTrack treadmill is a heavy-duty treadmill designed specifically for stress test applications. The Quinton MedTrack Programmable controller is required to operate the treadmill. See Figure 2-1.



Figure 2-1. Quinton MedTrack ST65 Treadmill

2.1.1 Maintenance of the Treadmill

Routine maintenance for the Quinton MedTrack Treadmill involves:

- Confirming that the cable from the treadmill is securely connected to the back of the programmable treadmill controller.
- Daily visual inspection of walking belt for wear and to confirm that the belt is centered on rollers. Always check for potential hazards on treadmill.
- Cleaning surfaces after each test with disinfectant and towel. Make sure the deck does not get wet.
- A weekly check of speed and grade to ensure accuracy of treadmill calibration (see section on calibration).
- Weekly inspections of treadmill belt tracking and tension (see instructions below).

2.1.1.1 Belt Tension - Weekly Check

The belt tension should be adjusted whenever the belt slips or moves unsteadily during operation. Notify the chief technologist if the belt tension needs adjustment. Belt tension is adjusted as follows.

All technologists:

- Use the controls on the controller to start the treadmill at minimum speed and grade, then increase speed to 2.5 mph.
- Hold onto handrail for balance and walk heavily on the treadmill by marching flat-footed. If the belt hesitates or lags noticeably, the chief technologist will tighten the belt as described in the following steps.

Chief technologist:

- Locate the two tension bolts at the rear of the treadmill.
- Turn both tension bolts clockwise $\frac{1}{4}$ turn. Test the belt tension. Repeat if necessary until the belt runs smoothly without slipping. If more than three adjustments are necessary, a service call may be necessary.
- Stop the treadmill.

- Check the position of the rear roller guards and adjust if necessary (see section on rear roller guards below).

2.1.1.2 Belt Tracking – Weekly Check

All technologists:

- Notify the chief technologist whenever the belt moves to one side or the other (off center). The chief technologist will adjust the belt tracking as follows.

Chief technologist:

- **Stay off the belt when adjusting tracking.**
- Use the controls on the controller to start the treadmill at minimum speed and grade.
- Increase speed to 3.7 mph to make adjustments.
- If the belt moves to the right, turn the right tension bolt a quarter turn clockwise.
- If the belt moves to the left, turn the left tension bolt a quarter turn clockwise.
- After making an initial adjustment, run the treadmill for several minutes and observe how the belt tracks. Adjustments to belt tracking take several minutes to become apparent. If the belt continues to move off center, adjust accordingly until it is properly centered. **Do not tighten the belt too much as this will cause accelerated wear on the roller bearings.**
- Stop the treadmill.
- Check the position of the roller guards (see section on rear roller guards).

2.1.1.3 Rear Roller Guards - Weekly Check

All technologists:

- See Figure 2-2. Check the position of the rear roller guards each time you readjust the belt tracking or belt tension. The roller guards are located at the rear of the treadmill between the rear roller and the deck.
- If the gap between the roller and the guard exceeds 3/8 of an inch, notify the chief technologist.

Chief technologist:

- Adjust the guards when the gap between the roller and the guard exceeds 3/8 of an inch.
- Disconnect the treadmill power cord from the receptacle (outlet).
- Loosen, but do not remove, the two screws attaching the rear roller guard to the deck (hold nuts underside with your finger).
- Slide the rear roller guard towards the rear until the gap between the two is approximately 0.1 inch (the thickness of two quarters).
- Tighten the two mounting screws on the rear roller guards.
- Connect the power cord.

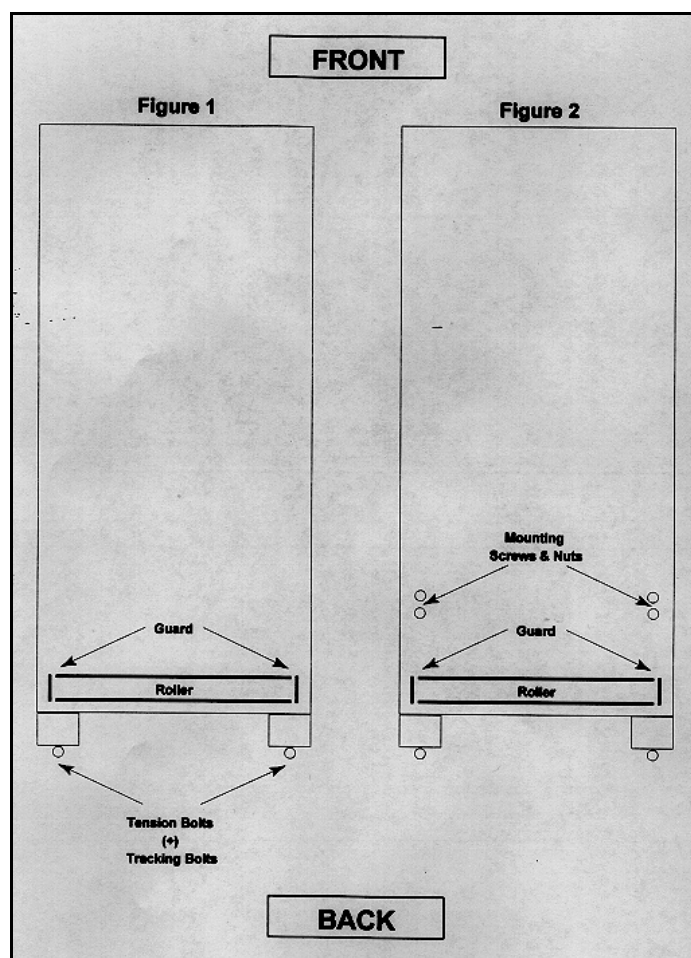


Figure 2-2. Treadmill calibration

2.1.2 Calibration of the Treadmill

Treadmill calibration should be checked weekly to ensure accuracy of testing results. However, if the treadmill is not within calibration specifications, a service technologist should be consulted.

2.1.2.1 Speed – Weekly Check

NOTE: This calibration is to confirm the validity of the belt speed. Section 2.2.2 deals with confirming that speed and grade settings on the treadmill controller are programmed correctly.

- Determination of belt length is essential to calculate belt speed. Use two pieces of masking tape to mark one spot on the belt and the second on the edge of the treadmill next to the belt.
- Measure the length of the belt in feet. (Belt length should be determined following any adjustment to the belt.)
- Make sure the belt is free of objects.
- Use the controller to start the treadmill and increase the speed to 2.5 mph.
- Set a timer for 3 minutes.
- Start the timer and begin counting the number of times the two pieces of tape meet (starting with zero).
- Divide the number of revolutions by the time (3 minutes) to obtain revolutions per minute.
- Multiply the revolutions per min. by the belt length and divide the product by 88 ft/min to obtain belt speed.
- **[# revs/min.* belt length)/88 ft/min = belt speed (mph)]**
- If speed readout on controller exceeds ± 0.2 mph of actual speed, repeat the previous steps.
- See Section 6.4.5 for data entry of these results in the equipment Quality Control screens.
- If treadmill still exceeds range, report this to the MEC manager. The MEC manager will call a service representative.

2.1.2.2 Elevation - Weekly Check

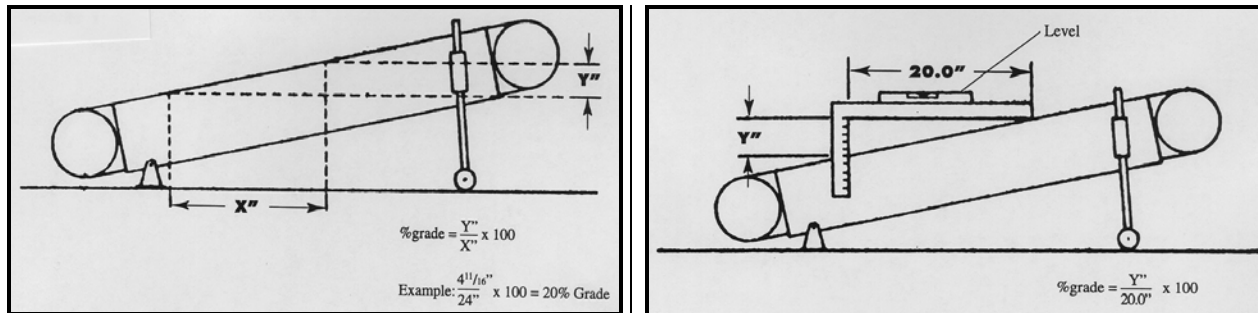


Figure 2-3. Calibration of elevation

All technologists:

- Check to make sure the treadmill is level prior to calibration of elevation using a level. If the treadmill is not level, make adjustments to level treadmill before continuing.
- Raise the treadmill elevation through its entire range and return to zero. This will allow the treadmill to perform a self-check.
- Raise treadmill to 20 percent grade.
- Using the carpenter's square and a level, measure the change in grade from low to high (rise over run). The change in grade should equal 4 12/16 inches for every 24 inches of length (or 2 2/8 inches for every 11 inches of length. See Figure 2-3.
- If the elevation error exceeds $\pm 1\%$ grade, repeat the previous steps.
- If the elevation still exceeds $\pm 1\%$ grade in error, report this to the MEC manager. The MEC manager will call a service representative.
- See Section 6.4.5 for data entry of these results in the equipment Quality Control screens.

2.2 Quinton MedTrack ST Programmable Controller

The MedTrack ST Programmable Controller is a computerized treadmill controller designed to regulate speed and grade for Quinton treadmills. See Figure 2-4. Eight different protocols have been programmed into the controller for NHANES. Each protocol is programmed such that the actual protocol

can be adjusted up or down one level depending on the sample person's (SP's) heart rate (HR) response and set criteria. Noted exceptions are Protocol 1 which can only increase to Protocol 2, and Protocol 8 which can only decrease to Protocol 7. Maximal treadmill speed is set to 3.7 mph to ensure SP safety.

The dimensions of the controller are 22.75" x 8.50" x 2.5" (57.79 x 21.59 x 6.35 cm) and the weight is 11 lbs. (5 kg).



Figure 2-4. Quinton MedTrack ST Programmable Controller

2.2.1 Maintenance of the Programmable Controller

The MedTrack ST Controller requires little maintenance. Wipe surfaces down weekly with a damp cloth to remove dirt and dust from the screen and inspect cables for unusual wear. Routine maintenance of the Colin STBP-780 BP monitor involves:

- Checking that the cable from the treadmill is connected **securely** to the back of the treadmill controller.

2.2.2 Calibration of the Programmable Controller

The Quinton MedTrack Controller does not require any specific calibration. The speed and grade for each of the eight exercise protocols on the treadmill controller will be confirmed on a weekly basis. The **chief technologist** will be responsible for this procedure.

2.2.2.1 Confirming the Speed and Grade Settings on the Treadmill Controller

NOTE: This calibration check is to determine that the speed and grade settings on the treadmill controller are programmed correctly. Section 2.1.2.1 deals with confirming the validity of the belt speed.

Chief technologist:

- Get Speed and Grade Table by Protocol and Stage (See Appendix J). Use this table to check the settings on the treadmill controller.
- Press the Power button on the treadmill controller to turn the power on.
- To enter programming mode, simultaneously press Stop Belt, Cool Down, and Start Course, then release them.
- The message 'Program' scrolls across the display.
- Press Enter.
- Press 'Input +' to go to Protocol 1.
- Press 'Next Stage'.

- The yellow dot below ‘Warm-up (current)’ will be flashing to indicate the controller is now in Protocol 1, current warm-up (the assigned exercise protocol).
- Check the speed and grade on the treadmill controller with the speed and grade on the Speed & Grade Table by Protocol and Stage to confirm that the treadmill settings are the same as listed in the table.
- ***NOTE:** If the numbers are not the same, do not attempt to change the settings. Report this immediately to the component specialist at the home office. The component specialist will confirm the settings and give instructions on how to change the settings if necessary.*
- Press ‘Next Stage’ to advance to Stage 1, Current. Check the speed and grade on the treadmill controller with the speed and grade on the table. (As noted above, the yellow dot will be flashing under the stage that the treadmill is currently set. Each time ‘Next Stage’ is pressed, the treadmill controller moves to the next stage and the yellow dot flashes under the new stage.)
- Press ‘Next Stage’ to advance to Stage 2, Current. Confirm the settings for speed and grade.
- Press ‘Next Stage’ to advance to Recovery, Current. Confirm the settings for speed and grade.
- Press ‘Next Stage’ to advance to Stage 1, Lower. Confirm the settings for speed and grade.
- Press ‘Next Stage’ to advance to Stage 2, Lower. Confirm the settings for speed and grade.
- Press ‘Next Stage’ to advance to Recovery, Lower. Confirm the settings for speed and grade.
- Press ‘Next Stage’ to advance to Stage 1, Higher. Confirm the settings for speed and grade.
- Press ‘Next Stage’ to advance to Stage 2, Higher. Confirm the settings for speed and grade.
- Press ‘Next Stage’ to advance to Recovery, Higher. Confirm the settings for speed and grade.
- Repeat the last 6 steps to check the second set of settings for the next lower and next higher protocols.
- After the second ‘Recovery, Higher’ is confirmed, press ‘Enter’.
- Press ‘Input +’ to advance to Protocol 2.

- Press ‘Next Stage’ to go to ‘Warm-up, Current’ for Protocol 2. (yellow dot will be flashing under this stage).
- Continue this sequence as listed above to confirm speed and grade for all protocols 1 through 8. There are 16 settings to check for each protocol.
- When all settings are confirmed with the settings on the table, press ‘Enter’ to save the settings.
- Simultaneously press Stop Belt, Cool Down, and Start Course, then release them to exit the programming mode.
- Check that this was completed in the weekly Quality Control Log on the Integrated Survey Information System (ISIS). (Section 1.3 provides a brief explanation of ISIS, the data entry system that is used for this study.)

2.3 Colin STBP-780 Automatic Blood Pressure Monitor

The Colin STBP-780 is an automated electronic heart rate and blood pressure (BP) monitor capable of accurate readings at rest and during exercise. See Figure 2-5. The unit assesses heart rate via wires connected to four electrodes placed on the thorax and abdomen. Blood pressure is assessed during deflation of the cuff via two microphones in the cuff. The front display provides clear, easy to read measurements of heart rate, systolic and diastolic BP, elapsed time, and error messages. When turning the system on, a Self-Check is performed automatically. If an error is detected, see Section 2.9.2.

The field for the systolic blood pressure at the top left corner of the blood pressure monitor displays an estimate of systolic BP during deflation. This number flashes as the measurement is being taken. Once the systolic and diastolic blood pressure and the heart rate are measured, all three values are displayed on the monitor and downloaded to the computer screen and system database during the test.

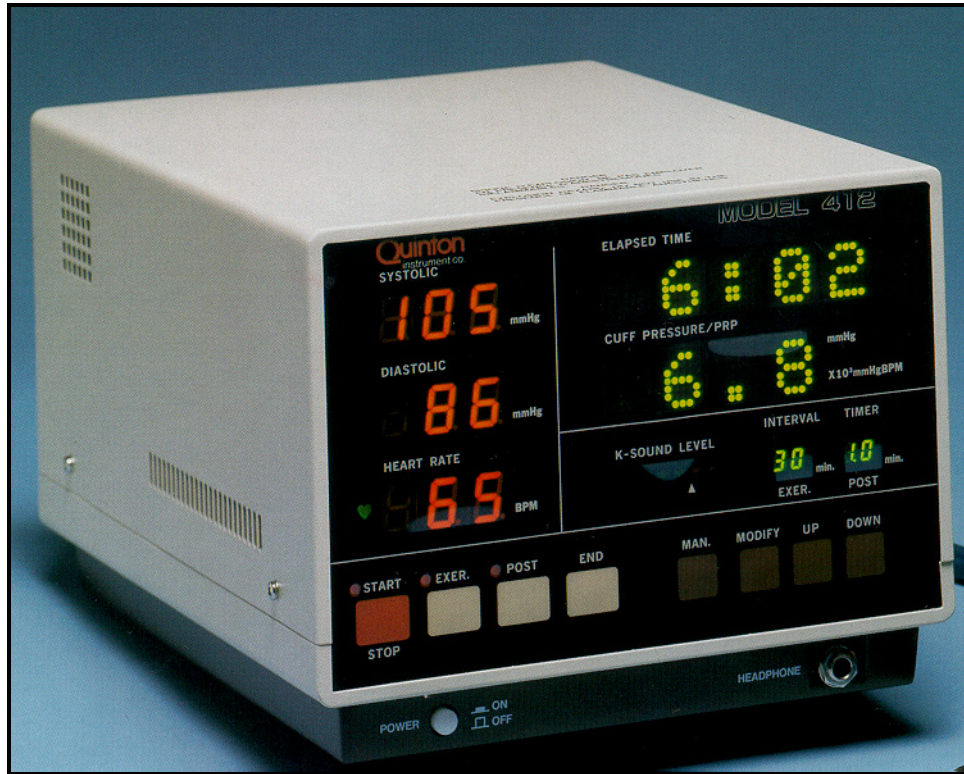


Figure 2-5. Colin STBP-780 Automatic Blood Pressure Monitor

2.3.1 Maintenance of the Automatic Blood Pressure Monitor

Routine maintenance of the Colin STBP-780 BP monitor involves:

- Checking that hoses and microphone wires are securely connected to the jacks.
- Checking that the computer cable is securely connected to the back of the BP monitor.
- Wiping surfaces clean daily with a clean dry cloth. If necessary, use a mild soap and water solution. DO NOT use alcohol to clean surfaces.
- Clean BP cuffs after each use with disinfectant or alcohol and allow drying.
- Ensure BP cuffs are stored properly. DO NOT store the cuff such that stress is placed on the connection of the microphone to the cuff.

2.3.2 Calibration of the Automatic Blood Pressure Monitor

The calibration of the pressure amplifier inside the STBP monitor will be checked each week with a mercury manometer. The reading on the STBP monitor should be within +/- 5mmHg from the reading on the mercury manometer. If the difference between the readings differ by more than 5 mm Hg, the STBP monitor will need to be returned to the manufacturer for calibration.

- Weekly calibration check procedures are outlined below:
 - Turn off the power switch for the STBP monitor.
 - Get portable mercury manometer, and Y-connector with rubber bulb from the room supply box.
 - Set up the mercury manometer on the computer cart.
 - Connect one end of the Y-connector to the air tubing on the mercury manometer.
 - Connect second end of the Y-connector to the inflation outlet at the back of the STBP monitor.
- Use the following steps to check the calibration of the STBP with the mercury manometer. The calibration will be checked at these five ranges:
 1. 220-250
 2. 180-220
 3. 120-180
 4. 70-120
 5. 0-70
- While pressing the END switch, turn POWER switch on.
- Press MANUAL switch to set unit in the MANUAL mode. The word “MAN” is displayed on the LED of the ELAPSED TIME indicator.
- While pressing the UP switch, press the START switch.
- Raise the pressure in the mercury manometer to 250 mmHg. Tighten the screw to maintain the mercury at a constant level.
- In about 1 second, the pressure values are displayed on the STBP monitor.

- Compare these values with the value on the mercury manometer.
- The numbers on the STBP LED display should be within +/- 5 of the reading at eye level on the mercury manometer.
- Loosen the screw and slowly deflate the cuff to a reading on the manometer in the next range.
- Press the RESET switch to deflate pressure.
- Press the MANUAL switch to release the MANUAL mode.
- Repeat these steps for each of the ranges listed above.
- If the number is within +/- 5, enter a check beside this item on the Quality Control Screen. See Figures 6-9 to 6-11.

If the BP calibration checks are not within the acceptable range (more than 5):

- Check connections with Y-connector, air hoses, and cuff for leaks.
- If the **BP calibration checks are not within the acceptable range**, enter the difference between the mercury manometer reading and the reading on the STBP monitor in the 'Result' field (Example: Difference = 8mmHg).
- Enter the reading on the manometer and the reading on the STBP monitor in the 'Comments' field (Example: Manometer = 110; STBP=118).
- Notify the MEC manager and chief technologist. Make a note of this in the 'Comments' section (Example: Reported to the MEC manager).
- If the difference between the readings differ by more than 5 mm Hg, the STBP monitor will need to be returned to the manufacturer for calibration.
- **NOTE: Notify the home office if the difference is greater than 3mmHg.** This is an 'early warning alert'. Continue to use the monitor for pressure measurement. This allows time to have the unit replaced and serviced in a timely manner without compromising data.

2.3.3 Mercury Manometer (Used for Calibration)

The mercury manometer is calibrated when it is manufactured and, once calibrated, re-calibration is unnecessary. However, regular inspection is necessary to eliminate conditions that could cause the blood pressure measurement to be read as erroneously high or low.

- Check to see that the level of mercury in the glass tube is zero. The level of the mercury in the calibrated glass tube should always be at the zero line when the manometer is on a level surface with the inflation system disconnected. Tip the manometer gently to the right and then to the erect position. If the top of the mercury column does not return to zero, replace the equipment.
- Check the shape of the meniscus - it should be a smooth, well-defined curve.
- Check that the mercury rises easily in the tubing and that the mercury column does not bounce noticeably when the valve is closed.
- Check for cracks in the glass tube to make sure it is securely in place.
- Check cap at top of the calibrated glass tube to make sure it is securely in place.
- Check cuff, pressure bulb, and manometer for cracks or tears.
- Check pressure control valve for sticks or leaks.
- Use the following procedure to check for air leaks:
 - Put the male luer plug in the female luer adapter on the Y-connector.
 - Connect the male connector on the manometer to the female connector on the Y-connector.
 - Inflate to 250 mm Hg.
 - Open valve and deflate to 200 mmHg and close valve.
 - Wait for 10 seconds. If mercury column falls more than 10 mm Hg, there is an air leak in the system.
- Never attempt to repair the equipment yourself.
- Contact the MEC manager to have equipment sent for repair or replacement. The manometer will be sent to the home office and from there will be sent to Baum for repair or replacement.

2.3.4 Mercury Spills and Leaks

A mercury manometer will be used for the calibration check. Mercury is a metallic substance which gives off a toxic vapor when exposed to the atmosphere. Temperature, ventilation, and sunlight affect the level of the vapor's concentration. Mercury vapors will permeate the skin surface and are poisonous when inhaled.

Check the cap at the top of the calibrated glass tubing. If it is not securely closed, the mercury could leak out. Loss of air and mercury will occur if the glass tube is broken. Care should be taken in handling the manometer to prevent this. If the tube appears cracked, check for any spilled mercury and replace the equipment if necessary.

The following procedure is recommended for handling spilled or leaking mercury:

- Contact the MEC manager immediately to report the incident and receive instructions. The Mercury Spill Kit contains all the materials needed for clean up.
- The MEC manager will determine what action should be taken. If necessary, he/she may call the local contact to report such spills. This agency may want to make a followup visit to the facility to check for levels of mercury in the exposed area.
- Do not touch the mercury with your bare hands or attempt to vacuum or clean up the spill yourself.
- The procedures for cleaning up the mercury are different depending on the surface where the spill is detected.
- If the spill is small you may be directed to use the following procedures.
- For leakage or spillage on a hard surface (e.g., hard floor, table, etc.):
 - Get the Mercury Spill Kit from the physician's examination room.
 - Put on the green protective gloves
 - Use the mercury (HG Absorb) sponge.
 - Remove the sponge from the plastic zip closable bag.
 - Dampen the sponge with water.
 - Wipe the area contaminated with mercury. Do this slowly to allow for complete absorption of all free mercury. The chemical layer (Hg Absorb Powder) on the sponge will absorb the mercury droplets.

- After finishing with the Hg Absorb sponge, place it back into its plastic zip closable bag.
- Place the manometer case and mercury sponge into separate plastic bags and secure with tape. Return to the MEC manager.
- Obtain replacement equipment.
- For leakage and/or spillage on a soft or absorbent surface (e.g., rug, etc.):
 - Get the Mercury Spill Kit from the physician's examination room.
 - Put on the green protective gloves.
 - Turn off heat or air conditioning to avoid spreading vapors to other rooms in the MEC.
 - Open a window if possible to ensure adequate ventilation to the outside for the room where the spill occurred.
 - Use the mercury (Hg Absorb) sponge, if possible. See directions above.
 - Wet the MERCSORB™ powder with water. Mercury will react with powder, forming a metal/mercury amalgam.
 - Wipe or sweep wetted powder over all cracks and hard to reach locations for maximum pickup.
 - Pick up amalgam by sponging or by using the small sweep and dustpan provided in the Mercury Spill Kit.
 - Obtain replacement equipment.

2.4 SECA Floor Scale Model 815

The SECA model 815 floor scale is used to measure weight in this component. It has a digital display indicator head fitted at the back of the platform with the connecting cable stored in the compartment underneath the head. The scale is a load cell model with a weighing range of 0-136 kilograms (kg). It operates with a standard 9 V alkaline battery. In order to open the battery compartment, open the battery lid underneath the head. Connect the battery terminals, then insert the battery and close the cover.

The reading of the scale is accurate to 0.25 kg over the entire weighing range. If two values are displayed alternately in the 0.25 kg. range, then the exact weight is between the two values and the

intermediate weight should be entered. For example, if the scale is reading between 70 and 70.25 kg, 70.13 kg should be entered in the weight field. Other instructions include:

- If “SUP” appears on the display, it signals that the scale is overloaded and cannot be used for this measurement.
- If no weight display appears when an SP is on the scale, have the SP step off the scale, press the **ON** button and wait for the display 0.0.
- If - - - appears on the display, press the **ON** button and wait for the display 0.0.
- If “Err” appears on the display, have the SP step off the scale, press the **ON** button, and wait for display 0.0.
- If “bAt” appears on the display, change the battery.

2.4.1 Maintenance and Calibration of the Floor Scales

The SECA scale should be calibrated at the beginning of each stand and weekly.

Start of Stand. At the beginning of each stand, check to see that the scale is operating properly with the batteries in place, and then standardize the portable scale to the Toledo scale on the MEC using the calibration weights found in the body measurements room of the MEC. Procedures for standardizing the SECA scale are given below. Any problems with the scale should be reported to the MEC manager immediately.

To standardize each SECA scale:

- Perform the standardization procedures in the body measures room of the MEC.
- Press the ON button of the SECA scale and wait for the display 0.0.
- Place the calibration weights on the scale in increments of 50 pounds, starting with 50 and continuing to 250.
- If the scale is off by 1 pound or more with the 5 weights placed on it, inform the MEC manager and use the other scale.

Weekly. Prior to each examination, place a 50-pound weight on the scale to roughly check the accuracy. Note the check in the QC log. If there is any reason to believe that the scales are not accurate, do a full calibration as described above. Record the calibration in the QC log. If the scale is off by 1 pound or more, inform the MEC manager.

2.5 SECA Portable Stadiometer Model 222

The SECA model 222 portable stadiometer is attached to the wall in the CV Fitness room. The detachable floor piece has been modified to be large enough for the SP to stand on and the plastic headpiece must be lifted and placed on the SP's head. The two vertical measuring bars have both centimeters and inches imprinted on them. Measurements are read in centimeters at the orange plastic line where the two measuring bars connect.

2.5.1 Maintenance and Calibration of the Stadiometer

Calibrate the stadiometer at the beginning of each stand and weekly during the stand. The procedures are as follows:

Start of Stand and weekly: Make sure the measuring column is pushed completely into the floor piece by checking that it is inserted up to the etched line.

- a. Place the calibration rod on the floor of the stadiometer.
- b. Place the horizontal bar of the stadiometer firmly against the top of the calibration rod. The stadiometer should read 100 cm.
- c. Document the performance of the calibration procedure in the QC log.
- d. If the reading is off by > 1 cm, inform the MEC manager. Use the stadiometer until a backup is sent.

2.6 Description of Supplies

2.6.1 ECG Electrodes/Alcohol Prep Pads/Abrasive Pads

Foam stress test V electrodes (1.5 “) from Vermont Medical will be used with the ECG chest leads to monitor the heart rate during the exam. Alcohol prep pads will be used to prepare the site for attachment of electrodes. Marquette abrasive pads will be used to remove old cells from the skin surface to improve adherence of the chest electrodes.

2.6.2 Running Shoes

The criteria that are important to consider when assessing whether or not the SP’s footwear is appropriate for the treadmill test are the presence of arch supports, heel cushions, and traction. If the SP does not bring footwear that is appropriate and safe for this test, acceptable footwear will be provided. A supply of women’s and men’s running shoes are kept in a shoe rack in the cardiovascular fitness room in each mobile examination center (MEC).

Examples of appropriate footwear are running shoes, casual or leisure style shoes, and modern athletic hiking boots. Some examples of inappropriate footwear include pumps, sandals, women’s or men’s dress shoes, hard sole boots or shoes (work boots, traditional hiking boots), any boot or shoe that has a heel for aesthetic purposes, and any shoe with cleats (soccer, golf, baseball, etc.).

2.6.3 Mesh Vests

If a SP has chest hair that covers the sites for electrode placement, the area **will not** be shaved. See Section 3.8.5. In situations where the chest hair makes adherence of the electrode to the skin difficult, a mesh vest will be used to help secure the electrodes and stabilize the leads.

2.7 Repair of Equipment

Contact for Repair or Replacement of Parts

Quinton Treadmill and Programmable Controller

Quinton Instrument Company
3303 Monte Villa Parkway, Bothell, WA 98021-8906
Phone: 206-402-2000
Fax: 206-402-2001

STBP Monitor and BP Cuffs

Colin Medical Instruments Corp.
5850 Farinon Drive, University Technology Park
San Antonio, Texas 78249
Phone: 800-829-6427
Fax: 210-696-8808

Mercury Manometer:

W. A. Baum Co. Inc.
Copiague, New York 11726
Phone: 516-226-3940
Fax: 516-226-3969

2.8 Equipment Manuals

The following equipment manuals are kept in the CV Fitness room.

- Medtrack ST 55 & ST 65 Treadmills Operator Manuals (Quinton);
- Medtrack ST 55 & ST 65 Treadmills Service Manuals (Quinton);
- Medtrack ST Programmable Controller Operator and Service Manual (Quinton); and
- Stress Test Blood Pressure Monitor Model STBP 780 Operation & Service Manual (Colin Medical Instruments Corporation).

2.9 Troubleshooting

2.9.1 Quinton MedTrack ST 65 Treadmill and Controller

The following table (2-1) may be used to troubleshoot some common problems with the treadmill and programmable controller.

Table 2-1. Troubleshooting problems with the Quinton Med Track ST65 treadmill and controller

PROBLEM	POSSIBLE CAUSE	REMEDY
Treadmill will not run.	Treadmill and/or monitor power cord is not plugged in	Plug in power cords.
	Monitor power off	Turn on controller.
	Controller cable disconnected or damaged	Plug in and secure controller cable. Replace if damaged.
	Circuit breaker for treadmill room reads "OFF"	Set the circuit breaker switch on the treadmill to "ON."
	Emergency stop button activated	Turn emergency stop button counter-clockwise to deactivate.
	Internal problem	Call authorized service rep.
Walking belt too far left or right.	Improper belt tracking	Adjust tracking as described in Section 2.3.1. If problem persists, call authorized service rep.
Walking belt slips, but front roller turns.	Improper belt tension	Adjust belt tension as described in Section 2.3.1. If problem persists, contact authorized service rep.
Walk belt hesitates; adjusting belt tension is ineffective.	Internal drive belt slipping	Service required. Call authorized service rep.
Treadmill will not change grade.	Excess weight on treadmill	Max load is 400 lbs.
	Internal problem	Service required. Call authorized service rep.
Circuit breaker trips during normal operation.	Power fault	Service required. Call authorized service rep.
Treadmill does not run; Exxx appears on display.	Problem with electronic circuitry	Record error number and call service rep.
	Internal problem	Service required. Call authorized service rep.
Other error messages appear on controller.	Varied	Record error message and call service rep.
Treadmill will not reach maxspeed.	Speed limit control is activated	Do not change!

2.9.2 Colin STBP-780 Blood Pressure Monitor

The following table (2-2) may be used to troubleshoot problems with the STBP monitor.

Table 2-2. Troubleshooting problems with the STBP monitor

DISPLAY	SYMPTOM	VOICE	PROBABLE CAUSE
Check ECG*	ECG trigger cannot be detected for 5 seconds.	Please check ECG.	A. ECG connectors are disconnected. B. ECG lead-select is not proper. C. The electrodes are not attached correctly and electrical noise is interfering. D. The ground wire is not attached correctly and electrical noise is interfering. E. Because of the extraordinarily strong ECG signal, ECG is detected as noise.
Check cuff	The inflation exceeds 15 seconds.	Please check cuff.	A. The capability of the pump-up motor has declined. B. Power supply voltage is fluctuating. C. Air is leaking. D. Cuff connector has become loose.
Check SYS	Third reinflation starts during REST MODE.	The safety valve is open.	A. The microphone detects noise. B. There is line noise.
Check MIC* Check MIC.* Check MIC!* Check MIC?*	The input signal from the microphones cannot be collected.	Please check microphone.	A. The microphones are not properly located on the artery. B. The signal cannot be detected; cuff may be wrapped upside down. C. The microphone is inferior. D. Microphone cord is not connected or is broken.
FAIL	In the self-test, an abnormality has been detected.	Machine failure.	Hardware failure. Call authorized service representative.
NOISE		None	The increase or decrease between 2 consecutive R wave readings exceeds 25%.
BATT		None	The voltage of the memory back-up battery goes down below 2 volts. Call authorized service rep.

3. PROTOCOL

The Cardiovascular Fitness component is composed of two sections. The first section will include shared exclusion questions and blood pressure measurement. The second section will include the preparation and performance of the treadmill test. In addition, some SPs will be excluded by medication review and/or review of shared exclusions asked in the Physician's exam.

3.1 Exclusions to the CV Fitness Component

SPs are excluded from the Cardiovascular Fitness component based on selected medical history, medications, physical limitations, and edit limits on heart rate, blood pressure, and irregular beats. These exclusions will be determined from several sources. Physical limitations and other safety exclusions are determined as part of the Shared Exclusion questions asked in several components. Review of medications and medical exclusions are determined based on questions asked in the Household Interview and then subsequently reviewed by the MEC physician. Measurements of heart rate, blood pressure and irregular beats are determined as part of the Blood Pressure section in the Physician's Exam or in Section 1 of the CV Fitness Exam. The procedures for each of these exclusions are outlined below.

3.1.1 Shared Exclusion Questions

Shared exclusion questions are safety exclusions that are shared with other components in the MEC. These questions are asked only once in the MEC and if they have been asked in a previous component, the questions and responses will be displayed in read-only format in subsequent components. A response that indicates an exclusion to one or more components will send a flag to the Coordinator System and the SP will be blocked from the appropriate components. The shared exclusion questions that block SPs from CV Fitness are listed below:

1. Do you have any amputations of your legs and feet other than toes? Where is the amputation?
2. How much do you weigh without clothes or shoes?
3. Do you have a pacemaker or automatic defibrillator?

4. Are you currently pregnant? How many weeks?

SPs are excluded from CV Fitness if they have an amputation of one or both legs based on physical limitation. A weight of greater than 350 pounds will exclude the SP due to a weight limitation of the treadmill. SPs are excluded for safety reasons if they have a pacemaker or automatic defibrillator or if females are greater than 12 weeks pregnant. See Chapter 4 for specific details on completing the data entry for these exclusions.

3.1.2 Medical History

SPs are asked specific questions in the Household Interview about their medical history and physical limitations. These Physical Activity Readiness questions are used by researchers and clinicians to determine whether individuals can safely perform a fitness test on a treadmill. The questions asked in the Household Interview are listed below:

1. Has a doctor ever said you have a heart condition and that you should only do physical activity recommended by a doctor?
2. Do you feel pain in your chest when you do physical activity?
3. In the past month, have you had chest pain when you were not doing any physical activity?
4. Do you lose your balance because of dizziness?
5. Do you ever lose consciousness?
6. Do you have a bone or joint problem that could be made worse by walking?
7. Do you know of any other reason why you should not walk on a treadmill?

If the SP responds 'Yes,' 'Don't Know,' or 'Refused' to one or more of these questions, the physician in the MEC will review the specific question(s) with the SP during the Physician's Exam to determine if the SP should be excluded from the treadmill test based on this/these question(s). If the physician determines that there is no indication for exclusion to the treadmill test based on this/these question(s), the flag for exclusion will be removed. If all other reasons for exclusion are negative, the SP will be cleared for the treadmill test.

If the SP gives a response of ‘No’ to all the above questions, these questions will not be flagged for review by the Physician in the MEC.

In addition, SPs who are greater than 12 weeks pregnant will be excluded. A urine test for pregnancy will be completed and a self-report of pregnancy status will be obtained. If these conditions are confirmed in the Household Questionnaire, the SP is excluded from the CV component before they enter the mobile examination center (MEC). The system will record the component status as ‘Not Done’ with the comment ‘safety exclusion.’ The SP will not need to go to the CV room in the MEC to have this exclusion recorded.

3.1.3 Medications

SPs are excluded from the CV Fitness component if they are taking medications that may indicate the SP is being treated for a medical condition that would be a contraindication to performing a treadmill test in the NHANES setting. In addition, SPs are also excluded if a medication they are taking may affect the validity of the test results (i.e. beta blockers). Exclusionary medications include anti-arrhythmics, nitrates, beta-blockers, cardiac glycosides, ophthalmic beta-blockers, and antihypertensive/betablocker/diuretic combinations. See Appendix C for a detailed list of exclusion medications with class codes. This list is updated every 3 months if necessary to include recently released medications.

Information on medications is collected in the Household Interview and displayed in the Physician’s Exam application on the CV Review for Exclusion Medication screen. (See Exhibit 3-1.) If an SP reported taking a medication that is on the exclusionary medication list, the system will flag the SP for exclusion to CV Fitness. In addition, any reported prescription medications will flag that SP for review by the MEC physician.

At the beginning of each session, the MEC physician will review the Exclusion Medication screen and will confirm flagged exclusions by checking the reported medications with the current list of exclusion medications. The physician will also check all reported prescription medications to confirm that no exclusion medications were reported that did not flag an exclusion. If an exclusion medication is confirmed the ‘Exclude from CV’ box will be checked. The system will block the SP from CV Fitness and set the Component status for CV Fitness to ‘Not Done’ with the comment ‘safety exclusion.’

Exhibit 3-1. CV Review for Exclusion Medications

SP ID	SP Name	Appt Type	Age	Gender	On Meds?	Exclude from CV	Reviewed
725210	THOMAS DOMINGUEZ	P	46 years	Male	Y	<input type="checkbox"/>	<input checked="" type="checkbox"/>
517835	ISABEL DOMINGUEZ	P	45 years	Female	Y	<input type="checkbox"/>	<input checked="" type="checkbox"/>
756084	EDUARDO GOMEZ	P	45 years	Male	Y	<input type="checkbox"/>	<input checked="" type="checkbox"/>
438386	ESTELLA RODRIGUEZ	P	37 years	Female	Y	<input type="checkbox"/>	<input checked="" type="checkbox"/>
995359	OTTO GREDONE	P	36 years	Male	Y	<input type="checkbox"/>	<input checked="" type="checkbox"/>
164942	ROGER COMBS	P	35 years	Male	Y	<input type="checkbox"/>	<input checked="" type="checkbox"/>
342942	GEORGE SMYTHE	P	30 years	Male	Y	<input type="checkbox"/>	<input checked="" type="checkbox"/>
916056	KAREN SMYTHE	P	30 years	Female	Y	<input type="checkbox"/>	<input checked="" type="checkbox"/>
620079	OLIVIA GREDONE	P	26 years	Female	Y	<input type="checkbox"/>	<input checked="" type="checkbox"/>

Prescription Medications
ETHMOZINE
ethmozine

Close

3.1.4 Be All Question

If the SP has completed all the exclusion questions and still remains eligible, an inclusive question is asked to confirm that there are no other reasons for not completing a treadmill test. This provides the SP with an opportunity to mention any reason that might not have been asked specifically. The question reads:

Since you were interviewed in your home on {Household Interview Date} have there been any changes in your health or medications that would prevent you from walking on a treadmill for the fitness test?

3.1.5 Exclusions Based on Heart Rate and Blood Pressure

The resting heart rate and blood pressure measurements taken in the Physician’s Exam or in the Blood Pressure section of the CV Fitness Exam will be used as the baseline measurements that are reviewed for exclusion from the treadmill test. SPs will be excluded from the CV Fitness component if one or more of the following criteria are present:

- Heart rate greater than 100 beats per minute;
- Systolic blood pressure greater than 180 mmHg;
- Diastolic blood pressure greater than 100 mmHg; and
- Irregular beats greater than 3 per minute.

If one or more of the above are present, the system will exclude the SP from the treadmill test. The CV Fitness Component Status will be set to ‘Not Done’ with the comment ‘safety exclusion.’

3.2 Introduction to Component

It is important to log on to the computer data entry system as soon as you can after entering the examination room. However, you should provide the sampled participants (SPs) with a brief explanation of the treadmill test as you are walking from the reception area to the treadmill test room. Many sampled participants may have never walked on a treadmill and may be a little apprehensive about this component. Make frequent eye contact with the SP when you are explaining the test and make sure he or she is listening and understands what you are saying. Below is an example of the introduction you may use. This is not a standard script so you may use your own words.

Suggested Introduction to the Component (Not a standard script): English Version

“In this exam we want to get some information about your cardiovascular fitness or the fitness of your heart. We will be asking you to walk on the treadmill while we monitor your heart rate and blood pressure. I will explain this in more detail in a few minutes but first I want to ask you a few

questions. Please come over here near the computer while I scan your identification number into the system.”

Suggested Introduction to the Component (Not a Standard Script): Spanish Version

“En este examen queremos obtener alguna información acerca de su condición cardiovascular o la condición del corazón. Le pediremos que camine sobre la máquina de andar mientras le monitoreamos la frecuencia cardíaca (los latidos del corazón) y la presión de sangre. Explicaré esto con más detalle en unos pocos minutos pero primero quiero hacerle algunas preguntas. Por favor venga aquí cerca de la computadora mientras anoto con el escáner su número de identificación en el sistema.”

3.3 Measurement of Height and Weight to Determine Body Mass Index

Once you are in the Cardiovascular (CV) Fitness room, log on to the Integrated Survey Information System (ISIS) and confirm the SP’s identity. (Section 1.3 provides a brief explanation of ISIS, the data entry system that is used for this study.)

After you have logged on to the system, check the first screen to determine if the height and weight information is displayed on the screen. If the SP was in the anthropometry component prior to this test, the height and weight will be uploaded and displayed on the ISIS screen. If the information is not displayed, you will need to measure the SP’s height and weight using the stadiometer and floor scales in the room. The system will use the height and weight measurements to calculate the body mass index and use it in the calculation to determine predicted VO_2 max. You must use the same precision to take the height and weight measurements in this component as you use in the anthropometry component.

3.3.1 Height

Follow these steps to take the SP's height:

1. Ask the SP to remove his or her shoes if necessary.
2. Place the stadiometer a few inches away from the wall. Check to be sure the measurement column on the stadiometer is completely inserted into the floorpiece. Pull the sliding top bar section up and open the head piece to allow the SP to step under the head piece.
3. Ask the SP to stand erect on the floorboard with his or her back to the vertical piece of the stadiometer and the wall. The SP should not be leaning against the stadiometer.
4. Ask the SP to evenly distribute weight on both feet. The heels are placed together with the feet pointed slightly outward at a 60 degree angle. The arms hang freely by the sides of the trunk with palms facing the thighs. (See Figure 3-1.)
5. Position the head in the Frankfort horizontal plane. The head is in the Frankfort plane when the horizontal line from the ear canal to the lower border of the orbit of the eye is parallel to the floor and perpendicular to the vertical backboard. Many people will assume this position naturally, but for some it may be necessary to make a minor adjustment. If required, gently tilt the head up or down until proper alignment is achieved with the eyes looking straight ahead. Once correctly positioned, ask the SP to inhale deeply and to stand fully erect without altering the position of the heels.
6. Lower the headpiece snugly to the crown of the head with sufficient pressure to compress the hair.
7. Hold the top sliding bar in place at the junction and ask the SP to step out away from the stadiometer.
8. Record the measurement in centimeters (measurements printed on right side of bar) at the orange line on the measuring bar.

3.3.2 Weight

Follow these steps to take the SP's weight:

1. Make sure the scale weighs in kilograms by checking the switch on the underside of the digital display.
2. Place the scale on the floor.

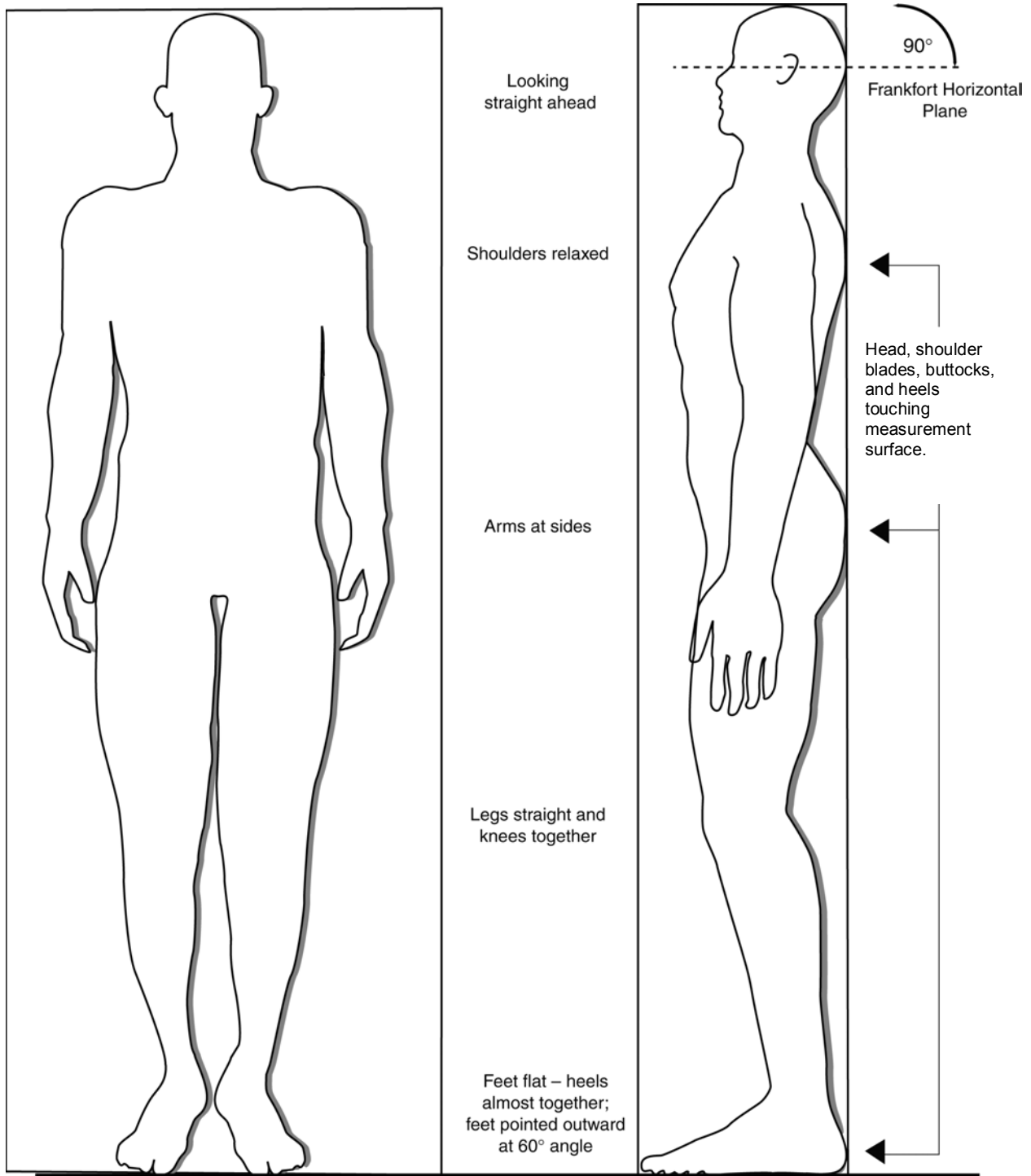


Figure 3-1. Correct body placement for height measurement

3. Switch on the scale by pressing the **ON** button; 888.8 will appear on the digital display.
4. Have the SP remove his or her shoes and any heavy outer clothing such as sweaters, jackets, etc.
5. As soon as the display switches to 0.0, have the SP step on the scale with his or her feet positioned in the center.
6. Ask the SP to stand straight and remain still.
7. Wait about 4 seconds for the weight to display on the digital readout.
8. Record the weight in kilograms in the weight field.
9. Ask the SP to step off the scale. The scale switches off automatically after 30 seconds.

If the SP's weight is in excess of 136 kilograms, follow these steps for using two scales:

1. Perform steps 1 through 4 (as listed above).
2. Place the two scales side by side, but not touching each other. The scales do not need to be parallel to each other. They can be angled to facilitate SP positioning.
3. Instruct the SP to place one foot on the center of each scale platform.
4. Ask the SP to stand straight and remain still as described above in step #6.
5. Note the two weights given, following the same procedure as if one scale were used.
6. Add the weights displayed on each scale and enter the sum of the two weights in the weight field.
7. Perform step #9 as listed above.
8. (Note: If the SP weighs more than 350 pounds [158.8 kilograms], he or she is excluded from this component due to weight limitation on the equipment).

3.4 Checking SP's Footwear

SPs are asked to bring comfortable walking shoes to the MEC; checking the SP's footwear is an important part of the preparations for the treadmill test. See Section 2.6.2 for a description of appropriate and inappropriate footwear for this test. If the SP does not have appropriate footwear, select a pair of running shoes from the stock supply in the exam room. Do not begin the physical activity

readiness questions while the SP is putting on his or her shoes or engaged in any other activity. You should have the SP's full attention when you are asking these questions to ensure that he or she is listening and understands what you are asking.

3.5 Determination of Physical Activity Readiness Code

Each SP will be assigned an exercise protocol based on his or her sex, age at interview, body mass index, and a Physical Activity Readiness (PAR) Code. The PAR Code is determined by a series of questions to approximate the amount of time spent in physical activity per week over the past year. See Section 3.5.1 and 3.5.2 for the English and Spanish version of these questions.

- Wait until the SP has his or her shoes on and is ready to listen to your questions. It is important that you read the questions clearly and that this is the only activity you and the SP are doing. Make sure that the SP is listening to you and make frequent eye contact while administering these questions.
- Read the introductory sentence and the first three questions completely before accepting a response.
- If the SP gives a response before you have read all three options, tell the SP that you are required to read all three responses before he or she gives an answer.
- If the response is refused or 'Don't Know,' the SP is excluded from the exam. The component status would be set to 'Not Done' with the comment 'Unable to calculate protocol.'

3.5.1 Questions to Determine PAR Code: English Version

First Level of Questions

- *I am going to ask you several questions to describe your **typical physical activity level**. Please try to answer as accurately as possible. Please wait until I read all three questions before you give me your answer.*
 1. Would you say that you did **little or no regular** recreation, sport, or physical activity?

OR

2. Would you say that you participated **regularly** in recreation or work requiring **modest physical activity**?

OR

3. Would you say that you participated **regularly** in **heavy physical exercise**?

If the SP needs further clarification on the meaning of modest versus heavy, use the following examples:

Modest physical activities include: walking, calisthenics, bowling, weight lifting, yard work.

Heavy physical activities include: jogging, swimming, cycling, rowing, tennis, and basketball.

Enter 1, 2, or 3 in the system.

Second Level of Questions for Little or No Regular Activity

- If the response to the first set of questions is 1 (little or no regular activity), the system will go to a set of questions to further classify the SP's physical activity level. A PAR code will then be assigned based on the response and be used to determine predicted VO₂ max.
- Read both questions before accepting a response.
 1. Would you say that you **avoid walking or exertion**, for example always use the elevator, drive whenever possible instead of walking?

OR
 2. Would you say that you walk for pleasure, routinely use stairs, occasionally exercise sufficiently to cause heavy breathing or perspiration?
- A PAR code will then be assigned as outlined below:
 - If response is 1 (avoid walking), the PAR Code will be assigned as 0.
 - If response is 2 (walk for pleasure), the PAR Code will be assigned as 1.

Second Level of Questions for Regular Participation in Modest Physical Activity

- If the response to the first set of questions is 2 (participated regularly in modest physical activity), the system will go to a set of questions to further classify the SP's

physical activity level. A PAR code will then be assigned based on the response and be used to determine predicted VO₂ max.

- Read both options before accepting a response.

Would you say that you participate regularly in recreation or modest physical activity for:

1. **10 to 60 minutes per week?**

OR

2. **More than 60 minutes per week?**

- A PAR code will then be assigned as outlined below:

- If response is 1 (10 - 60 minutes per week), the PAR Code will be assigned as 2.
- If response is 2 (more than 60 minutes per week), the PAR Code will be assigned as 3.

Second Level of Questions for Participated Regularly in Heavy Physical Activity

- If the response to the first set of questions is 3 (participate regularly in heavy physical exercise), the system will go to a set of questions to further classify the SP's physical activity level. A PAR code will then be assigned based on the response and be used to determine predicted VO₂ max.
- Read all options before accepting a response.

Now I am going to ask for some more detail on the amount of heavy physical exercise you did. I am going to give you four options.

Would you say that you participated regularly in heavy physical activity for:

1. less than 30 minutes per week

OR

2. 30 to 60 minutes per week

OR

3. 1 to 3 hours per week

OR

4. more than 3 hours per week

- The PAR Code will be assigned as outlined below:
 - If response is 1 (less than 30 minutes per week), the PAR Code will be assigned as 4.
 - If response is 2 (30-60 minutes per week), the PAR Code will be assigned as 5.
 - If response is 3 (1-3 hours per week), the PAR Code will be assigned as 6.
 - If response is 4 (more than 3 hours per week), the PAR Code will be assigned as 7.

3.5.2 Questions to Determine PAR Code: Spanish Version

- If Spanish is the first language of the SP, the system can be changed to the Spanish version of the PAR Questions.

Le voy a hacer varias preguntas para describir su **nivel típico de actividad física**. Por favor trate de responder tan precisamente como sea posible. Por favor espere hasta que yo lea las tres preguntas antes de darme su respuesta.

1. Diría que usted hizo **poca o ninguna** actividad **regular** de recreación, deporte, o física?

O
2. ¿Diría que usted participó **regularmente** en recreación o trabajo que requería **actividad física moderada**?

O
3. ¿Diría que usted participó regularmente en ejercicios físicos pesados?

Actividades físicas moderadas incluye: caminar, calistenia, bolos, levantamiento de pesas, trabajo en el (patio/jardín).

Actividades físicas pesadas incluye: trotar, nadar, andar en bicicleta, remar, jugar tenis, y baloncesto.

1. ¿Diría que usted evita caminar o hacer esfuerzos (por ejemplo, siempre toma el ascensor, conduce en lugar de caminar cada vez que es posible.)?

O

2. ¿Diría que usted camina por placer, rutinariamente usa las escaleras, ocasionalmente hace ejercicio suficientemente como para que le cause respiración agitada o transpiración?
3. ¿Diría que usted participó regularmente en actividades de recreación o físicas moderadas por:
 1. **10 a 60 minutos por semana?**
O
 2. **Más de 60 minutos por semana?**
 - Ahora le voy a preguntar algunos detalles más sobre la cantidad de ejercicio físico pesado que usted hizo. Le voy a dar cuatro opciones.
 - ¿Diría que usted participó regularmente en actividades físicas pesadas ...
 1. **menos de 30 minutos por semana,**
O
 2. **30 a 60 minutos por semana,**
O
 3. **1 a 3 horas por semana,**
O
 4. **más de 3 horas por semana?**

3.6 Determination of Predicted VO₂ Max

The system will use the following formula based on the PAR Code, age of SP at interview, body mass index, and sex of SP to calculate the predicted maximal oxygen consumption (VO₂ max).

$$\text{Predicted VO}_2 \text{ max} = 56.363 + [1.921 * (\text{PA-R})] - [0.38 * (\text{Age at interview})] - [0.754 * (\text{BMI})] + [10.987 * (\text{F}=0, \text{M}=1)]$$

- Physical Activity Readiness (PAR) Code = 0-7 (see Section 3.5)
- Body Mass Index (BMI) = body weight(kg) / height squared (m²) (see Section 3.3)

- Age predicted maximal heart rate ($HR_{max} = 220 - \text{Age}$)

3.7 Determination of Exercise Protocol

The system will use the predicted maximal oxygen consumption (see Section 3.6) to determine the predicted exercise protocol to use for the SP. See Appendix H for the table that is used to determine the predicted exercise protocol for each individual SP. This table has eight exercise protocols. Some modifications have been made to the predicted exercise protocol to modify the workload assigned to specific age groups. The rationale for this is to facilitate a better prediction of the workload for these specific groups.

If the SP is 12 through 18 years of age, the system will subtract the predicted protocol by 2 and for SPs 19 through 25 years of age, the system will subtract the predicted protocol by 1 to get the assigned protocol for these age groups.

Exercise protocols 1 and 8 will not be used for 12- through 49-year-olds. In addition, exercise protocol 2 will not be used for SPs 12 through 18. SPs with a predicted exercise protocol of 1 will be reassigned to protocol 2, while SPs with a predicted exercise protocol of 8 will be reassigned to protocol 7. For SPs who are 12 through 18 years and assigned a protocol of 1 or 2, the exercise protocol will be reassigned as protocol 3.

This assigned protocol will be displayed on the Treadmill Test screen. The assigned protocol may be adjusted up or down one level based on the SP's response (see Section 3.12) with the following exceptions. SPs 12 through 49 years cannot be increased to protocol 8 or decreased to protocol 1. In addition, SPs 12 through 18 years cannot be decreased to protocol 1 or 2.

3.8 Preparation for Treadmill Test

Prior to beginning the treadmill test, a blood pressure cuff for automatic blood pressure monitoring and chest electrodes for monitoring heart rate will be attached to the SP. The SP's footwear should be checked once again before starting the test to confirm that laces are tied or shoes are on properly.

3.8.1 Preparation of Skin and Placement of Electrodes

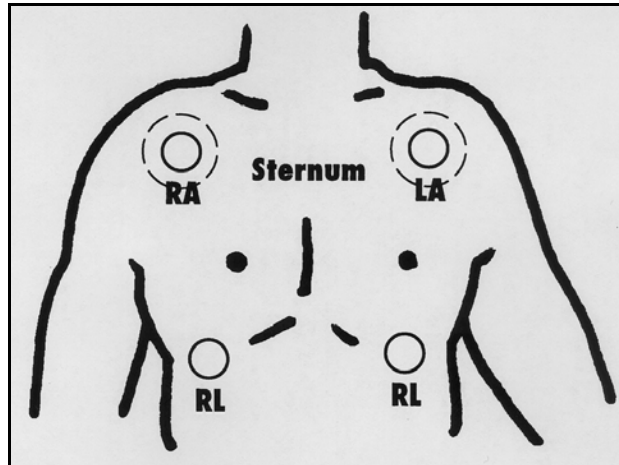


Figure 3-2. Site for placement of electrodes (1)

- The following sites will be used for electrode placement. See Figure 3-2.
 - RA: below the distal end of the right clavicle, on the superior aspect of the pectoralis major.
 - LA: below the distal end of the left clavicle, on the superior aspect of the pectoralis major.
 - RL: right anterolateral surface of the abdomen at the level of the umbilicus.
 - LL: left anterolateral surface of the abdomen at the level of the umbilicus.
 - If the individual has a large amount of body hair, the electrodes can be moved slightly to give better contact with the skin. To avoid unintended injury or discomfort to the SP, this site will not be shaved. Move the electrodes approximately 2 inches laterally. See the outer limit circles on RA and LA in Figure 3-2.
- Preparation of the sites for attachment of electrodes:
 - Briskly wipe the skin at placement site of electrode with a skin preparation swab to remove any oils or lotions on the skin.
 - Lightly abrade the skin (no more than 6-8 swipes) with a fine abrasive strip covering an area the size of the electrode.

- Attach electrode to the four sites by pressing around the outer edges of electrode first to maximize adherence and then press gently on the center of the electrode to enhance the contact of the electrode gel to the skin surface.
- Clip the RA, LA, RL, and LL leads to the appropriate electrodes.
- For female SPs, hand them the two top electrodes (RA and LA) and ask them to thread the leads up underneath the gown and hand them to you. After the SP has done this, take the leads and attach them to the appropriate electrodes.

3.8.2 Selection of Arm for Blood Pressure Monitoring

The Colin STBP-780 is an automated electronic heart rate and blood pressure monitor that will be used to measure blood pressure and heart rate during the treadmill test. See Chapter 2 for a description and picture of this monitor.

- The right arm will be used for blood pressure monitoring.
- Do not use the right arm if any of the following are present on that arm: wound, rash, cast, edema, bandages, or any condition that would cause discomfort to the SP or would prevent accurate measurement of blood pressure.
- Do not use the arm if the SP has a dialysis shunt in that arm.
- If the SP has had a radical mastectomy do not use the arm on the side of the mastectomy. Use the opposite arm. If the SP has had a bilateral mastectomy, do not measure the blood pressure in either arm. The SP will be excluded from the exam.
- If the right arm cannot be used, use the left arm.
- Do not use the left arm if any of the conditions listed above for the right arm are present. In this situation, enter “Could Not Obtain” in the system.
- Enter “right, left, or could not obtain” for Arm Selected.
- If “right” or “left” is selected, go to cuff size and enter the cuff size that will be used.
- If “could not obtain” is selected, the SP will be excluded due to inability to monitor blood pressure. The system will display a message to ask you to confirm your selection. If you select yes, another message will be displayed as “SP excluded due to safety considerations/physical limitations informing you that the SP has been excluded from the test.” The system will go to the Component Status screen; the Status will be set to “Partial” with the comment “physical limitation.”

3.8.3 Selection of Cuff Size and Placement of Cuff

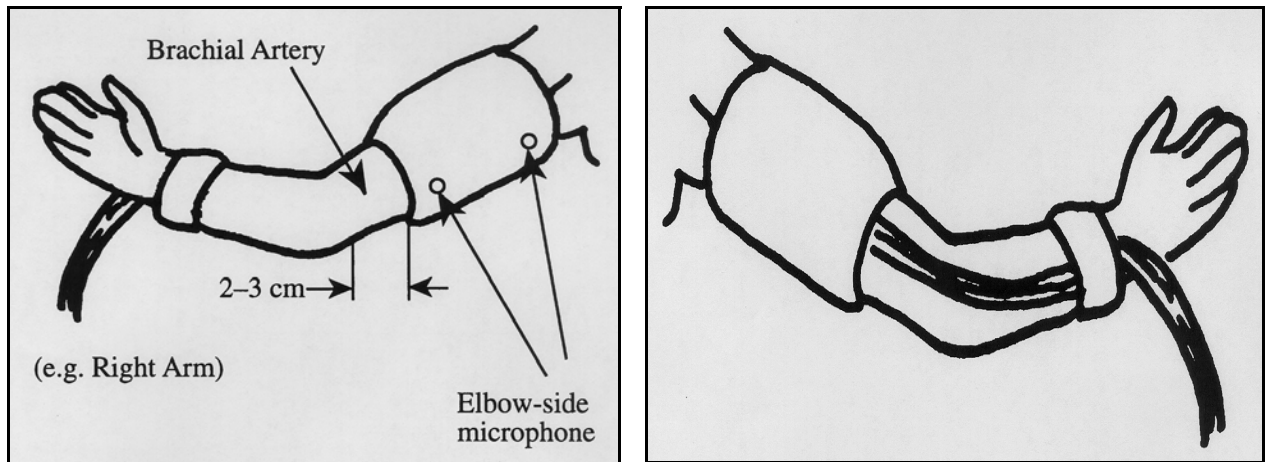


Figure 3-3. Site for placement of electrodes (2)

- See Figure 3-3 above for position of cuff on arm.
- The MEC physician will measure the arm to determine the appropriate cuff size and will write the cuff size used on the shoulder or sleeve of the SP's gown. The same size cuff should be used for this exam.
- Attach appropriately sized blood pressure cuff (child, adult, or large adult) on the arm selected. The bladder of the cuff should be about two-thirds of the arm circumference.
- Palpate for the brachial artery and position the cuff so that the two microphone sensors are located directly over the brachial artery.
- Position the cuff snugly around the upper arm, 1 inch above the antecubital space.

3.8.4 Room Temperature

Ideal room temperature for the treadmill test should be 68-72 degrees Fahrenheit. Perspiration on the skin will interfere with the adherence of the electrodes to the skin and higher temperatures may increase the effort needed by the SP to perform the test.

The room temperature will be automatically recorded by integration with a Nimbus digital thermometer. If integration fails, the room temperature will be entered manually by entering the temperature reading on the digital thermometer. The room should be kept within the ideal temperature

noted above. If necessary, turn up the air conditioner and turn on the fan. It may be more comfortable for the SP if the fan is turned on after the test has started and he or she is warming up.

3.8.5 Mesh Vest

If male SPs have chest hair that interferes with the attachment of the electrode:

- The electrode can be moved slightly to give better contact with the skin. The electrode may be positioned approximately 2 inches from the optimal site for electrode placement.
- If there is a lot of hair on this spot, try to move the hair aside and place the electrode on the site with as much skin contact as possible.
- In this situation, optimize the situation and use the mesh vest. Record this on the Exam Preparation screen in ISIS. The default for this field is set to 'No' and is disabled for females.

3.9 Treadmill Test

3.9.1 Setup of Colin STBP Automatic BP Monitor

- See Sections 3.8.1 through 3.8.3 for procedure for electrode placement and cuff selection and placement.
- Press Power button to turn on power.
- SELF TEST is displayed on the Elapsed Time/Cuff Pressure Indicator.
- The BP monitor performs a self-test.
 - If an error is found:
 - a. **FAIL** is displayed on the Elapsed Time/Cuff Pressure Indicator.
 - If **no error** is found the following are displayed for about 5 seconds:
 - a. The year on the Systolic Indicator,
 - b. The month on the Diastolic Indicator, and
 - c. The date on the Heart Rate Indicator.

- FIRST REST is displayed on the Elapsed Time/Cuff Pressure Indicator if:
 - The ECG cable is connected properly to the ECG connector on the rear panel.
- Heart Rate is displayed in the Heart Rate Indicator.
- CHECK ECG is displayed on the Elapsed Time/Cuff Pressure Indicator if:
 - ECG electrodes are not connected properly. Check that the leads are in the correct position. Check that the ECG cable is connected tightly to the port.

3.9.2 Setup of Programmable Controller and Treadmill

A set of predetermined test protocols based on the predicted maximal oxygen uptake would be programmed into the controller. After the SP has been logged into the system, the system will calculate and display the predicted VO₂ max based on the information described above.

- Press Power to turn on the power to the controller and the treadmill.
- Press Enter (this enters 150 as weight - do not change this).
- Press Input + twice to bring up the different protocols.
- Press Input + to move forward through the protocols.
- Press Input - to move back through the protocols.
- The protocol number appears to the left of the multifunction display (see diagram).
- The exercise time appears to the right of the multifunction display.
- Each vertical column in the tricolor display represents one stage of the protocol.
- The green LEDs indicate the preprogrammed grade.
- The red LEDs indicate the preprogrammed speed.
- There are 16 horizontal lights on the treadmill display. See Figure 3-4 on page 3-34.
 - The first 4 lights represent the current protocol (Warm-up, Stage I, Stage 2, and Recovery).
 - The next 3 lights represent the next lower protocol (Stage 1, Stage 2, and Recovery).

- The next 3 lights represent the next higher protocol (Stage 1, Stage 2, and Recovery).
- The next 3 lights represent the next lower protocol again (Stage 1, Stage 2, and Recovery).
- The next 3 lights represent the next higher protocol again (Stage 1, Stage 2, and Recovery).
- A blinking light represents the current stage.

The next lower and next higher protocols are repeated twice in case the technologist overshoots the desired protocol when manually changing the protocol if needed. The controller only allows advancing to the next protocol. You are not able to go back to the previous protocol on the controller without advancing through all 16 levels.

3.9.3 Obtaining Pretest Blood Pressure and Heart Rate

- When the Pretest Measurement screen comes up on ISIS, the system will automatically enter the room temperature from an integrated digital thermometer.
- The system will then give an auditory message:

Check footwear, attach chest electrodes and BP cuff. Then explain the treadmill test.

- The SP's footwear is checked when he or she comes in the room. The SP is asked to put on appropriate footwear at this time. This check is just an additional measure to confirm that the SP has proper footwear and that laces are tied if appropriate, prior to starting the test.
- Attach electrodes and BP cuff as outlined in Sections 3.8.1 and 3.8.3.
- Explain the treadmill test to the SP following the standard script in Section 3.9.4 when attaching the electrodes and BP cuff or when capturing the blood pressure measurement.
- When the explanation is completed, have the SP stand quietly with his or her arms down by the side while the baseline measurements are being obtained.
- Confirm that the blood pressure monitor power button is ON.
- Press CAPTURE on the ISIS screen to tell the system to start the baseline BP measurement. It will take 35 to 45 seconds for the measurements to be taken.

- Pretest blood pressure and heart rate will then be displayed on BP MONITOR and will be automatically captured in the system.
- These values are not the official data points for blood pressure for the NHANES. The SP's resting blood pressure and heart rate are measured and recorded in the physician's office prior to the treadmill test. The pretest values obtained in the treadmill testing room simply indicate that the BP unit is functioning.
- When the blood pressure measurement is captured, the system will display a message "Demonstrate how to walk on a treadmill." Do not advance to the treadmill test screen until you have given this demonstration. See Section 3.9.5 for details.

3.9.4 Script for Explaining Treadmill Test

While you are attaching the chest electrodes and the blood pressure cuff you can explain the treadmill test to the SP. Below is a standard script that should be read exactly as written to ensure that each SP is given the same explanation for this test.

Explanation of Treadmill Test - Standard Script: English Version

"The purpose of the treadmill test is to estimate your cardiovascular fitness level. You will be walking on the treadmill at various speeds and grades. This is not a maximal test to exhaustion. We will stop when your heart rate reaches a certain level. While this is a very safe test, it is important that you let us know how you feel during the test. Please report any unusual symptoms that you have during the test such as chest pain, dizziness, nausea, or pain in your legs."

Explanation of Treadmill Test - Standard Script: Spanish Version

"El propósito de la prueba en la máquina de andar es calcular su nivel de capacidad cardiovascular. Usted caminará en la máquina a diferentes velocidades y grados. Esta no es una prueba máxima de esfuerzo. Pararemos cuando la frecuencia cardíaca (los latidos del corazón) alcance cierto nivel. Si bien esta es una prueba muy segura, es importante que nos diga cómo se siente durante la prueba. Por favor informe cualquier síntoma inusual que tenga durante la prueba tal como dolor en el pecho, mareo, náusea, o dolor en las piernas."

3.9.5 Demonstrating How to Walk on a Treadmill

After the blood pressure measurement is captured, you should give a brief demonstration of how to walk on a treadmill. The SP should be asked to step off the treadmill and stand to one side. Start the treadmill belt by pressing Start Belt on the treadmill controller, increase the speed to 2.0 mph and begin a brief demonstration of how to walk on the treadmill. You should hold onto the handrails, straddle the belt, and then gently “paw” the belt with one foot to get a feel for the movement, then step onto the belt and start walking slowly. The demonstration and explanation should include importance of standing up straight, taking long steps, relaxing, holding the head up and looking forward. You should demonstrate removing one hand at a time from the handrail and then walk comfortably on the belt. After this brief demonstration, step off the belt and press Stop Belt on the treadmill controller. Press Clear on the treadmill controller to reset the protocol.

After the data are captured and the demonstration is completed, press the ‘Next’ button on the ISIS screen to advance to the Treadmill Test screen.

- When the Treadmill Test screen comes up, the system displays and gives this auditory message:
Choose exercise protocol on treadmill controller. Have SP straddle the belt, then press START BELT.
- Select the predetermined protocol on the treadmill controller (the middle protocol on the ISIS screen).
- Get the SP to straddle the belt. Press START BELT on the treadmill controller.
- Increase the speed to 2 MPH.
- When you have completed this, click OK.
- Have the SP step on the treadmill and begin to walk.
- Tell him or her to use an upright posture and look straight ahead.
- If the SP is holding onto the handrail, tell the SP to drop one arm down by his or her side, then the other one.
- The SP should now be walking slowly on the treadmill and ready to begin the test.

- Allow the SP to hold onto the handrails for a little while into the Warm-Up Stage. Work with the SP to try to get both hands off the handrail by the end of the first minute in Warm-Up if possible.

3.9.6 Warm-up (00:00 - 02:00 Minutes)

- When OK was pressed as indicated above, the system will give an auditory message:
“Simultaneously press START on the ISIS screen and press START COURSE on treadmill controller.”
- Click ‘START’ on the ISIS screen to start the timer for the test.

AND
- Press ‘START COURSE’ on the treadmill controller to begin the Warm-up stage for the predetermined protocol selected for the SP.
- The timer will start for the 2-minute Warm-up. At the end of each stage, the timer will reset to zero and begin the next stage.
- When START COURSE is pressed on the treadmill controller, the treadmill will increase to the speed and grade for the predetermined Warm-up stage for the selected protocol.
- The system will automatically capture BP and HR at the end of each stage.
- Throughout the Warm-up stage, monitor the %HRmax scale on the ISIS screen. The SP’s HR should be up to the **60 percent range**. The %HRmax scale displays the HR in beats per minute for 50 percent, 60 percent, and 100 percent of PMHR for the SP. The SP’s current HR will be displayed on the BP monitor. If this reading is above or below the 50 percent to 60 percent range, follow the procedures below:
- If %HRmax is below 50 percent or above 60 percent, see Section 3.12 for protocol change procedure.
- If %HRmax is within the **50 percent - 60 percent range**, continue with present preprogrammed protocol.

3.9.7 RPE Explanation and Assessment

- Rating of perceived exertion (RPE) will be obtained at the end of Warm-up, Stage 1, and Stage 2. This scale will be explained to the SP during the first minute of Warm-up.

- If the SP is having trouble learning to walk on a treadmill, the explanation can be given after the SP is stable and comfortable. The priority is to get the SP walking on the treadmill with stability as soon as possible.

- At 00:15 minutes into Warm-up, the system will give an auditory message:

“Explain RPE”

The technologist will give the following explanation of RPE to the SP. This is a standard script and should be read exactly as it is written so that each SP is given the same explanation:

- See Section 3.10.1 for an exception to this in the final stages of Stage 2.

3.9.7.1 Explanation of Rating of Perceived Exertion (RPE) - Standard Script: English Version

“Please look at the chart on the wall in front of you. Every couple of minutes during the test, I will ask you to rate how hard you feel you are working overall. Please respond with a number from the scale. For example, if you feel that you are working at a very low level of effort, you might reply with a 6 or 7 (very, very light). On the other hand, if you feel you are working at a very high level of effort and cannot continue, you might reply with a 20 (maximal exertion). There is no right or wrong answer, simply rate your perceived level of exertion at the time I ask the question.”

3.9.7.2 Explanation of Rating of Perceived Exertion (RPE) - Standard Script: Spanish Version

“Por favor mire el gráfico en el muro frente a usted. Cada dos minutos durante la prueba, le pediré que califique qué tan fuerte siente que está trabajando en general. Por favor conteste con un número de la escala. Por ejemplo, si usted siente que está trabajando a un nivel de esfuerzo muy bajo, usted puede responder un 6 ó 7 (muy, muy liviano). Por otra parte, si usted siente que está trabajando a un nivel de esfuerzo muy alto y no puede continuar, usted puede contestar con un 20 (máximo esfuerzo). No hay respuesta correcta o errónea, simplemente califique su nivel de esfuerzo en el momento en que yo le haga la pregunta.”

- At 01:30 minutes into Warm-up, the system will give an auditory message:

“Get RPE assessment.”

- The technologist will ask the SP to give his or her rating of perceived exertion.

- The technologist will enter this number.
- At 1:50 minutes into Warm-up, the system will give an auditory message:
“Press NEXT STAGE on treadmill controller at 1 minute 57 seconds.”
- Technologist should press NEXT STAGE on the Treadmill Controller at exactly 01:57 minutes into Warm-up.
- This will change the treadmill to Stage 1.

3.9.8 Stage 1 (00:00 - 03:00 Minutes)

- The system will reset the timer to zero for Stage 1.
- Throughout the Stage 1, monitor the %HRmax scale on ISIS screen. Indicator should be within **60 percent - 80 percent range**.
- If the SPs HR goes above the 80 percent range:
 - Determine if the SP is OK by observing his or her color, breathing and gait for signs of severe fatigue and ask how he or she is doing.
 - Ask for the RPE. You do not have to record the RPE unless it is at the end of the stage.
 - If the SP looks OK, does not ask to stop, and RPE is not greater than 17, continue with the test.
 - Continue to monitor very closely for signs of exhaustion and stop the test if the SP’s symptoms warrant ending the test.
 - If the SP is not OK, the RPE is greater than 17, or the SP asks to stop, confirm that the SP understands what he or she is rating and if he or she still gives a rating of greater than 17, you go to the Recovery stage by pressing ‘Go to Recovery’ on the ISIS screen. See 3.13.2 for detailed procedures.
- At 02:30 minutes into Stage 1, the system will give an auditory message:
“*Get RPE assessment*”
- The technologist will ask the SP to give his or her rating of perceived exertion.
- The technologist will enter this number.

- The system will automatically set the BP monitor to start the BP measurement at 02:10 minutes into Stage 1. The end of Stage 1 BP and HR measurement will be captured at approximately 02:40 to 02:50 minutes into Stage 1.
- The system will give the following auditory message:
“Check heart rate on monitor.”
- The ISIS system will then display a visual message:
“Compare heart rate on blood pressure monitor with captured heart rate on ISIS screen. Enter a manual heart rate ONLY if they differ by more than 5 beats.”
- Note the heart rate on the blood pressure monitor and compare this number with the captured heart rate on the ISIS screen. If the captured heart rate on the ISIS screen does not differ by more than 5 beats from the heart rate on the BP monitor, click OK and continue the test.
- Five seconds before the stage ends, all the LEDs in that column flash, warning that the speed and grade will change soon.
- When the stage ends, the top and bottom LEDs turn yellow and the bottom LED in the next stage begins to flash.
- The treadmill will automatically change to the speed and grade for Stage 2.

3.9.9 Stage 2 (00:00 - 03:00 Minutes)

After 3 minutes in Stage 1, the speed and grade move to the values preprogrammed into the second stage for the selected protocol.

- Throughout Stage 2, monitor %HRmax scale on ISIS screen. The heart rate should be:
 - **below 90 percent for 12- through 18-year-olds, and**
 - **below 85 percent for 19- through 49-year-olds.**
- If the %HRmax is above 85 percent (or 90% for 12- through 18-year-olds):
 - Determine if the SP is OK by observing his or her color, breathing, and gait for signs of severe fatigue and ask how he or she is doing.
 - Ask for the RPE. You do not have to record the RPE unless it is at the end of the stage.

- If the SP looks OK, does not ask to stop, and RPE is not greater than 17, continue with the test.
 - Continue to monitor very closely for signs of exhaustion and stop the test if the SP's symptoms warrant ending the test.
 - If the SP is not OK, the RPE is greater than 17, or the SP asks to stop, confirm that the SP understands what he or she is rating. If he or she still gives a rating of greater than 17, you go to the Recovery stage by pressing 'Go to Recovery' on the ISIS screen. See Section 3.13.2 for detailed procedures.
- During the third minute of Stage 2, if %HRmax is above 100 percent, then press 'Go to Recovery' on the ISIS screen. See Section 3.13 for Stopping Procedures. Select 'Other' with comment '%HRmax > 100%' for Priority 2 Stopping Criteria.
 - At 02:30 minutes into Stage 2, the system will give an auditory message:
"Get RPE assessment"
 - The technologist will ask the SP to give his or her rating of perceived exertion.
 - The technologist will enter this number.
 - The system will automatically set the BP monitor to start the BP measurement at 02:10 minutes into Stage 2. The end of Stage 2 BP and HR measurement will be captured at approximately 02:40 to 02:50 minutes into Stage 2.
 - The system will give the following auditory message:
"Check heart rate on monitor."
 - The ISIS system will then display a visual message:
"Compare heart rate on blood pressure monitor with captured heart rate on ISIS screen. Enter a manual heart rate ONLY if they differ by more than 5 beats."
 - Note the heart rate on the blood pressure monitor and compare this number with the captured heart rate on the ISIS screen. If the captured heart rate on the ISIS screen does not differ by more than 5 beats from the heart rate on the BP monitor, click OK and continue the test.
 - If the heart rate is not captured on the ISIS screen or the observed HR on the blood pressure monitor is more than 5 beats from the captured heart rate, enter the observed HR in the manual heart rate field on the ISIS screen.
 - Five seconds before the stage ends, all the LEDs in that column flash, warning that the speed and grade will change soon.

- When the stage ends, the top and bottom LEDs turn yellow and the bottom LED in the next stage begins to flash.
- After 3 minutes in stage 2, the speed and grade move to the values preprogrammed into Recovery 1 for the selected protocol.

3.9.10 Recovery Stages 1, 2, & 3 (If Necessary)

- The system will automatically set the BP monitor to start the BP measurement at 00:10 minutes into Recovery 1. The end of Recovery 1 BP and HR measurement will be captured at 00:50 minutes into Recovery 1.
- The system will automatically set the BP monitor to start the BP measurement at 00:10 minutes into Recovery 2. The end of Recovery 2 BP and HR measurement will be captured at 00:50 minutes into Recovery 2.
- If $HR \leq 110$, an auditory message should remind technologist to stop the timer and stop the treadmill.

Press COOL DOWN on treadmill controller.

- Press COOL DOWN as directed above.
- Tell SP to grasp the front handrail and warn that the treadmill is about to stop.

“Press STOP BELT on treadmill controller. Congratulations, you have completed the test.”

- Press STOP BELT as directed.
- If $HR > 110$, proceed with Recovery 3. The system will give an auditory message:

“Proceed with Recovery 3”

- **Recovery 3:** The system will automatically set the BP monitor to start the BP measurement at 00:10 minutes into Recovery 3. The end of Recovery 3 BP and HR measurement will be captured at 00:50 minutes into Recovery 3. The system will give the following auditory message:

“Press COOL DOWN on treadmill controller.”

- Press COOL DOWN as directed above.

- Tell SP to grasp the front handrail and warn that the treadmill is about to stop.

“Press STOP BELT on treadmill controller. Congratulations, you have completed the test.”
- Press STOP BELT as directed.

3.9.11 End of Test

Assist the SP off the treadmill. It is normal to feel as if you are still moving, especially if you are not accustomed to walking on a treadmill. Remove BP cuff, disconnect the leads, and ask the SP to remove and dispose of the electrodes.

3.10 Procedure if Values Exceed Criteria

The system has the following edit limits set on these measurements:

- HR Stage 1 > 80 percent PMHR AND SP is exhausted and unable to continue.
- HR Stage 2 > 85 percent PMHR (>90% for 12 through 18 years AND SP is exhausted and unable to continue.)
- HR Warm-up, Stage 1 or Stage 2 > 100%.
- SBP > 260 mmHg
- DBP > 115 mmHg
- RPE > 17 (See below “Exception for RPE greater than 17 at end of Stage 2.”)
- If one or more of these measurements are above the acceptable criteria, the system will display a message:

“Check message on monitor.”
- The system will then display a message “(Data item) is not within the acceptable limits. Go to Recovery.”
- Press the ‘Go to Recovery’ button.

- The system will then give an auditory message:

“Press GO TO RECOVERY on ISIS screen and change treadmill controller to “Recovery Stage for current protocol.”

3.10.1 Exception for RPE Greater Than 17 at End of Stage 2

- If the RPE is greater than 17 in Warm-up, or Stage 1, go to Recovery. There is no exception at these two stages but you should confirm that the SP understands the concept. Confirm that the SP understands what he or she is rating and if he or she still gives a rating of greater than 17, go to Recovery.
- When you get the RPE assessment at 2:30 minutes into Stage 2, there is 15 to 20 seconds left before ISIS captures the heart rate and blood pressure.
- If the SP answers with a number greater than 17 AND the SP’s heart rate is within the acceptable limits for the end of stage 2:
 - Determine if he or she is able to continue for another 15 to 20 seconds.
 - Check for signs of distress by looking at the SP’s face, color, gait, respiratory rate.
 - Ask if he or she is able to continue for another 15 to 20 seconds.
 - Tell the SP the test is almost finished.
 - An example of a script is: “Do you think you can continue for another 15 to 20 seconds? The test will be over then and the treadmill will be slowing down in speed and the incline will become level. Are you sure you can continue?”
 - If the SP says he or she can continue for another 15-20 seconds, monitor continuously and allow the test to continue until the Stage 2 HR and BP are captured.
- Once the HR and BP are captured, if you think the SP can continue for another 10 seconds, allow the test to finish normally.
- If you think the SP cannot continue for another 10 seconds then:
 - Press ‘Next Stage’ on the treadmill controller to move the treadmill to the Recovery Stage.
 - Do not Press ‘Go to Recovery’ in ISIS.
 - (NOTE: You may not have to do this because the length of time is so short and the treadmill may have already advanced by the time you are ready to do this.)
 - Continue Recovery and Cool Down as usual.

3.11 Procedure if SP is Unable to Adhere to the Protocol

- Some people may not be able to walk on the treadmill without holding onto the handrails. The technologist should give the SP further instructions and encouragement. SPs are allowed to hold onto the handrail during Warm-up until they get accustomed to walking on the treadmill. The technologist should encourage SPs to remove their hands one at a time. During the treadmill test they are allowed to lightly touch the handrail with a finger, but they should not be grasping the handrail with their fingers or hands. If they are unable to do this, the test will not be valid.
- Some of the instructions that you may give to help the SP get accustomed to walking on the treadmill include reminding him or her to stand up straight, to keep his or her head up and look straight ahead, and to take longer steps.
- If the SP is still unable to adhere to the protocol, press GO TO RECOVERY on the ISIS screen.
- The system will record the time in the current stage.
- The system will reset the timer for 00:00 for Recovery.
- The system will give an auditory message:
“Change treadmill controller to Recovery Stage for current protocol”
- Change the setting on the treadmill controller by pressing NEXT STAGE until the Recovery stage is reached.
- The SP will go through the Recovery Stages 1 and 2.
- After the Recovery stages are completed, the system will go to the Priority 2 Stopping Criteria.
- Select “Unable to stop gripping handrails.”
- System will then go to Component Status screen. The component status will be set at “Partial.” Select “Unable to follow protocol” as the comment.

3.12 Procedure to Change Predicted Exercise Protocol

The goal of the predetermined exercise protocol is to elicit a heart rate that is approximately 75 percent of the predicted maximum heart rate (PMHR) by the end of the treadmill test. This goal is expected to be achieved gradually by stages: to elicit a HR response that is approximately 50 to 60 percent of PMHR during the Warm-up stage, then to elicit a HR response that is approximately 60 to 75

percent of PMHR during Stage 1, and last, to elicit a HR response that is approximately 70 to 80 percent of PMHR during Stage 2. There will be times where the selected protocol results in a HR response that is higher or lower than expected. When this occurs, the treadmill technologist will need to change to either an easier or more difficult protocol to help reach the goal. The decision to change the exercise protocol should be made during the beginning of the test—the Warm-up stage. No decision in changing the protocol should be made after the Warm-up stage. If the ISIS “Change Protocol” button is selected during Stage 1 or 2, the system will display this message: “The protocol cannot be changed after Warm-up.”

Throughout the Warm-up stage, monitor the **%HRmax** scale on ISIS screen. The SP’s HR should be within the **50 percent to 60 percent range**. The %HRmax scale on the computer screen displays the HR in beats per minute for 50 percent, 60 percent, and 100 percent of PMHR for the SP. The SP’s current HR will be displayed on the BP monitor. If this reading is above or below the 50 to 60 percent range, follow the procedures in 3.12.1 or 3.12.2 for changing the protocol. The decision to change the protocol must be made by 1 minute 30 seconds into the Warm-up stage to allow time to make all the necessary adjustments. If the protocol needs to be changed, the Change Protocol button on the ISIS screen should be pressed during the last 30 seconds in Warm-up, but the setting on the treadmill controller should not be changed until the treadmill automatically moves to the next stage. The treadmill is programmed to move to the next stage at specific times. If it is advanced to a new protocol during one stage, it will advance again to the next stage when the preset time is reached for the next stage.

There are 16 horizontal lights on the treadmill display. See Figure 3-4. The first four lights represent the current protocol (Warm-up, Stage 1, Stage 2, and Recovery). The next three lights represent the next lower protocol (Stage 1, Stage 2, and Recovery) and the next three lights represent the next higher protocol (Stage 1, Stage 2, and Recovery). The next lower and next higher protocols are repeated a second time to allow the technologist to advance to the correct protocol if he or she overshoots the protocol the first time. The controller does not allow moving backward through the protocols. You can only advance to the next protocol. A blinking light represents the stage that the SP is currently performing.

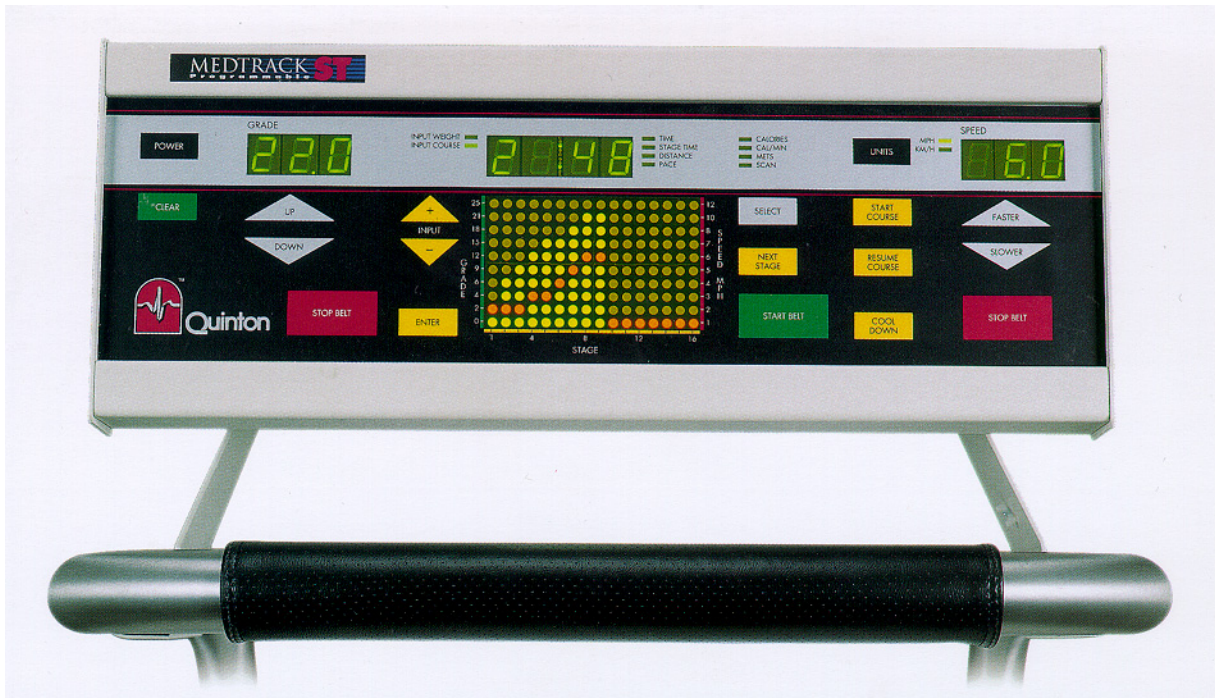


Figure 3-4. Treadmill controller - changing the exercise protocol

3.12.1 Increasing the Exercise Protocol

If %HRmax is below 50 percent PMHR in Warm-up, go to the next higher protocol at the beginning of Stage 1.

- Click on CHANGE PROTOCOL on the ISIS screen after 1 minute 30 seconds into Warm-up.
- Click on INCREASE and APPLY on the ISIS screen to change protocol to the next highest protocol.
- The system will give an auditory message:

“When this stage changes, change stage on treadmill controller to next higher protocol.”
- Do not change the stage on the treadmill controller until the current stage is completed and the treadmill has advanced to the next stage.

- As soon as the treadmill changes to Stage 1, press NEXT STAGE on the treadmill controller to get to Stage 1 for the next higher protocol. Watch the markings on the controller carefully and do not go past the desired setting.
- The system will automatically highlight the new stage and protocol on the ISIS screen.
- Confirm the speed and grade settings on the treadmill controller with the settings on the ISIS screen.

3.12.2 Decreasing the Exercise Protocol

If %HRmax is above 60 percent PMHR in Warm-up, go to the next lower protocol at the beginning of Stage 1.

- Click on CHANGE PROTOCOL on the ISIS screen.
- Click on DECREASE and APPLY on the ISIS screen to change protocol to next lowest protocol.
- The system will give an auditory message:
“When this stage changes, change stage on treadmill controller to next lower protocol.”
- Do not change the stage on the treadmill controller until the current stage is completed and the treadmill has advanced to the next stage.
- As soon as the treadmill changes to Stage 1, press NEXT STAGE on the treadmill controller to get to Stage 1 for the next lower protocol. Watch the markings on the controller carefully and do not go past the desired setting.
- The system will automatically highlight the new stage and protocol on the ISIS screen.
- Confirm the speed and grade settings on the treadmill controller with the settings on the ISIS screen.

3.12.3 Changing Exercise Protocol During Warm-up

Throughout the Warm-up stage, monitor the %HRmax scale on ISIS screen. See Section 4.4 for a description of the data entry procedures for changing the exercise protocol. The SP’s HR should

be within the **50 percent to 60 percent range**. The %HRmax scale on the computer screen displays the HR in beats per minute for 50 percent, 60 percent, and 100 percent of PMHR for the SP. The SP's current HR will be displayed on the BP monitor. If this reading is above or below the 50 to 60 percent range, follow the procedures below for changing the protocol. If the protocol needs to be changed, the Change Protocol button on the ISIS screen should be pressed during the last 30 seconds in Warm-up but the setting on the treadmill controller should not be changed until the treadmill automatically moves to the next stage. The treadmill is programmed to move to the next stage at specific times. If it is advanced to a new protocol during one stage, it will advance again to the next stage when the preset time is reached for the next stage.

If %HRmax is below 50 percent in Warm-up, go to the next higher protocol at the beginning of Stage 1.

- Click on CHANGE PROTOCOL on the ISIS screen after 1 minute 30 seconds into Warm-up.
- Click on INCREASE and APPLY on the ISIS screen to change protocol to the next highest protocol.
- The system will give an auditory message:
“When this stage changes, change stage on treadmill controller to next higher protocol.”
- Do not change the stage on the treadmill controller until the current stage is completed and the treadmill has advanced to the next stage.
- As soon as the treadmill changes to Stage 1, press NEXT STAGE on the treadmill controller to get to Stage 1 for the next higher protocol. Watch the markings on the controller carefully and do not go past the desired setting.
- The system will automatically highlight the new stage and protocol on the ISIS screen.
- Confirm the speed and grade settings on the treadmill controller with the settings on the ISIS screen.

If %HRmax is above 60 percent, go to the next lower protocol at the beginning of Stage 1.

- Click on CHANGE PROTOCOL on the ISIS screen.
- Click on DECREASE and APPLY on the ISIS screen to change protocol to next lowest protocol.

- The system will give an auditory message:
“When this stage changes, change stage on treadmill controller to next lower protocol.”
- Do not change the stage on the treadmill controller until the current stage is completed and the treadmill has advanced to the next stage.
- As soon as the treadmill changes to Stage 1, press NEXT STAGE on the treadmill controller to get to Stage 1 for the next lower protocol. Watch the markings on the controller carefully and do not go past the desired setting.
- The system will automatically highlight the new stage and protocol on the ISIS screen.
- Confirm the speed and grade settings on the treadmill controller with the settings on the ISIS screen.

3.12.4 Monitoring the Heart Rate During Stage 1

As discussed in Section 3.12, the only stage where a decision to change the exercise protocol should be made is during Warm-up. If an increase or decrease in the protocol is necessary, the change is made in the computer system during Warm-up and the treadmill controller is increased or decreased immediately after the treadmill controller advances to the next stage (first few seconds of Stage 1).

A decision to increase or decrease the exercise protocol should not be made during Stage 1. If the Change Protocol button is selected, the system will display this message: “The protocol cannot be changed after Warm-up.”

Throughout Stage 1, monitor the %HRmax scale on the ISIS screen. The SP’s HR should be within the 60 percent to 80 percent range. The %HRmax scale displays the HR in beats per minute for 60 percent, 80 percent, and 100 percent of PMHR for the SP. The SP’s current HR will be displayed on the BP monitor. If this reading is above or below the 60 percent to 80 percent range, follow these procedures.

- If %HRmax is < 60% continue with the current protocol.
- If %HRmax is above 80 percent of PMHR at any time in Stage 1, determine if the SP is OK by observing his or her color, breathing and gait for signs of severe fatigue, and ask the SP how he or she is feeling with a question such as: “How are you doing? We have approximately 4 minutes left in this part of the test. Do you think you can continue?”

- If the SP looks OK and does not ask to stop, continue with the test. Continue to monitor very closely for signs of exhaustion.
- If the SP is exhausted and wants or needs to stop, press Go to Recovery on the ISIS screen.
- If the %HR is above 80% when the data are captured near the end of Stage 1, a message will be displayed:

“HR greater than 80% PMHR. If SP is OK, continue with the test.”
- Follow the procedures noted above to determine if the SP can continue. If Go to Recovery is pressed on the ISIS screen, the system will then highlight the Recovery Stage for the current protocol.
- The system will give an auditory message to remind the technologist to change the setting on the treadmill controller. The message will say:

“Change treadmill controller to Recovery Stage for current protocol.”
- Press NEXT STAGE on the treadmill controller to get to Recovery for the current protocol. Watch the markings on the controller carefully and do not go past the desired setting. Press NEXT STAGE only once for this change.

3.12.5 Monitoring the Heart Rate during Stage 2

- The protocol should not be increased or decreased during Stage 2. If the Change Protocol button is selected, the system will display this message: “The protocol cannot be changed after Stage 1.”
- Throughout Stage 2, monitor the %HRmax scale on ISIS screen. If % HR max is >85 percent PMHR (>90 percent for 12- through 18-year-olds) a message will be displayed “HR greater than 85%/90% PMHR. If SP is OK, continue with the test.”
- Determine if SP is OK by observing the SP’s color, breathing and gait for signs of severe fatigue and ask the SP how he or she is doing with a question such as: “How are you doing? We have approximately 4 minutes left in the test. Do you think you can continue?”
- If the SP looks OK and does not ask to stop, continue with the test. Continue to monitor very closely for signs of exhaustion.
- If the SP is exhausted and wants or needs to stop, press Go to Recovery on the ISIS screen.
- The system will highlight the Recovery Stage for the current protocol.

- The system will give an auditory message to remind the technologist to change the setting on the treadmill controller. The message will say:

“Change treadmill controller to Recovery Stage for current protocol.”

- Press NEXT STAGE on the treadmill controller to get to Recovery for the current protocol. Watch the markings on the controller carefully and do not go past the desired setting. Press NEXT STAGE only once for this change.

If the SP’s heart rate goes above 100% at any time during the exam press Go to Recovery on the ISIS screen and change the treadmill controller to the Recovery Stage of the current protocol. If the %HR is above 100% when the data are captured near the end of Stages 1 or 2, a message will be displayed :

“HR > 100% PMHR. Heart rate is not within acceptable limits. Go to Recovery.”

As noted above, press Go to Recovery on the ISIS screen and change the treadmill controller to the Recovery Stage of the current protocol.

3.13 Procedure to Stop Treadmill Test Early

Technologists must be aware that not all SPs will be able to complete the treadmill test due to various reasons. From a safety perspective, it is critical that all technologists be very attentive to SPs regarding any signs/symptoms that may occur. There are two sets of stopping criteria and a different procedure will be used for each.

3.13.1 Priority 1 Stopping Criteria

- Pain or pressure in the chest.
- Pain in neck, jaw, or teeth.
- Pain in the shoulder or between the shoulder blades.
- Pain radiating down one or both arms.
- Moderate/severe leg pain or cramping.

- Lightheadedness, dizziness.
- Severe shortness of breath/wheezing.
- Change in skin color to bluish/grayish.
- Severe headache.
- Subject appears confused or agitated.
- Nausea.
- Unstable gait.
- Visual problems.

If one or more of the above criteria are present, the technologist will terminate the test, stop the treadmill, and initiate the following emergency action plan:

- Press EMERGENCY STOP on the ISIS screen. The system will give the following auditory message:
“Press COOL DOWN on treadmill controller, then press STOP BELT.”
- Assist the SP off the treadmill.
- Place SP in the supine position on the floor if necessary.
- Remain with the SP and call the physician.
- When the SP has stabilized, complete the information in the system.
- The system will record the time spent in the current stage at the time the EMERGENCY STOP button was pushed.
- The system will go to the Priority 1 Stopping Criteria (listed above).
- Enter the appropriate response. Check all that apply.
- The remaining stages and Recovery will not be completed.
- After the Stopping Criteria have been entered, press NEXT STAGE to go to the Component Status screen. The Status will be set to “Partial Complete” with the comment “Priority 1 Stopping Criteria.”
- Press the Finish button to exit this test.

3.13.2 Priority 2 Stopping Criteria

- SP HR during Warm-up, Stage 1 or Stage 2 exceeds 90 percent for 12- through 18-year-olds or 85 percent PMHR for 19- through 49-year-olds and SP is unable to continue.
- SP HR exceeds 80 percent PMHR during Stage 1.
- SP HR exceeds 100% during Warm-up, Stage 1 or Stage 2.
- Exercise blood pressure > 260 mmHg systolic and/or >115 mmHg diastolic.
- Significant drop (>20 mmHg) in systolic blood pressure during exercise.
- SP reports RPE > 17.
- Failure of systolic blood pressure to rise with increasing exercise intensity.
- Failure of heart rate to increase by more than 5 beats/minute during a given workload compared to the previous workload.
- Repeated noticed variability during a stage (**sudden** changes of \pm 30 beats/minute) after checking electrode connections.
- SP requests to stop test, or reports severe fatigue.
- Failure of testing equipment.
- SP is unable to stop gripping handrails (lightly touching handrails for balance purposes is allowed, but only if absolutely necessary). This criterion should cause the system to set the component status to “Partial” with the comment “unable to follow protocol.”
- Technologist discretion (technologist notices signs of severe exertion).

If one or more of the above criteria are present, terminate test and allow SP to actively cool down:

- Press “GO TO RECOVERY” button on the ISIS screen.
- The system will record the time spent in the current stage.
- The timer will be reset to 00:00 on the ISIS screen for the Recovery stages. The system will give an auditory message :

“Change treadmill controller to Recovery Stage of current protocol.”

- Press NEXT STAGE on the treadmill controller to get to Recovery for the current protocol. Watch the markings on the controller carefully and do not go past the desired setting. Press NEXT STAGE only once for this change.
- The SP will continue to walk on the treadmill for 1-3 minutes and the system will continue to monitor HR and BP at 1-minute intervals. The technologist may decide to terminate the test at any time based on the SP's condition.
- When the Recovery Stages are completed, the system will give the following auditory message:

“Press STOP on treadmill controller. Congratulations, you have completed the test.”
- The system will go to Priority 2 Stopping Criteria at the end of Recovery.
- Enter the appropriate response. Check all that apply.
- After the Stopping Criteria have been entered, press NEXT STAGE to go to the Component Status screen. The Status will be set to “Partial Complete” with the comment “Priority 2 Stopping Criteria.”
- Press the Finish button to exit this test.

3.14 Procedure to Recover/Restart an Exam

If the treadmill test has not gone past the first 15 seconds in Stage 1, you can restart the test.

This might occur in the following situations:

- The SP is not used to walking on a treadmill and jumps off. The SP may be able to continue the test if the instructions are repeated and the test is restarted;
- If the treadmill controller advances or is mistakenly advanced by more than 1 stage when Next Stage is pressed to move from Warm-up to Stage 1; or
- Other problems selecting the protocol on the treadmill controller.

In these situations the treadmill test may be restarted. The restart procedures below are also kept on the quick reference laminated cards in the CV Fitness room.

- Press **Cool Down** and **Stop Belt** to stop the treadmill.
- Confirm that the SP is willing to restart the treadmill test.
- Tell the SP that you are going to repeat the instructions step by step.

- Reset the treadmill controller to the appropriate exercise protocol.
- Repeat the instructions for getting on the treadmill.
- Have SP straddle the belt, press **Start Belt**.
- Have the SP start walking on the belt.
- Press **Start Course** on treadmill controller and '**Restart**' on ISIS screen.
- Continue the test as per protocol.

3.15 Recording Problems with Data Acquisition During the Treadmill Test

Record problems with equipment, protocol, and data measurement or capture on the data acquisition problem screen. Check all that apply. The categories are:

1. No problem.
2. Problem obtaining BP - the BP is not displayed on the BP monitor and not captured in ISIS. Check the stage(s) when this happened.
3. Problem obtaining HR (variability).
4. Problem with data capture - the BP is displayed correctly on the BP monitor but not correctly captured in ISIS.
5. Problem with electrodes (perspiration, chest hair, large chest/abdomen).
6. Problem with BP cuff (large arm, cuff slipped, bending/flexing of arm).
7. Problem with treadmill controller (accidental overshoot when advancing).

3.16 Component Status

The component status is set by the system based on predetermined criteria. If all the data were obtained and captured, the status is set to complete. If the test was stopped early or some of the data were not obtained or captured, the status will be set to partial. If the SP was excluded prior to the exam due to safety/exclusion reasons or refusal, the status will be set to not done. If the status is set to partial or not done, a comment is required. Some comments are set by the system based on predetermined criteria.

4. INTEGRATED SURVEY INFORMATION SYSTEM (ISIS) DATA ENTRY SCREENS

4.1 Shared Exclusion Questions

Shared exclusion questions are safety exclusions that are shared with other components in the MEC. These questions are asked only once in the MEC and if they have been asked in a previous component, the questions and responses will be displayed in read-only format in subsequent components.

Currently, the shared exclusion questions will always be displayed in read-only format in the CV Fitness component. See Exhibit 4-1. (This will be modified when other MEC team members are trained in blood pressure measurement.)

Exhibit 4-1. Shared Exclusions disabled from previous component

The screenshot shows a web browser window titled "Cardiovascular Fitness: Stand:410 Session:410791 11/05/2004 01:30 pm - 05:30 pm". The browser address bar shows "SP ID: 171464 Name: SMITH,ASHLEE Age: 21 years Gender: Female Date: 12/23/2004 Time: 01:18 PM". The page title is "Shared Exclusion Questions". The main content area contains the following questions and responses:

- 1a. Do you have any amputations of your legs and feet other than toes?
- 1b. Where is the amputation?
- 2. How much do you weigh without clothes or shoes? pounds
- 3. Do you have a pacemaker or automatic defibrillator?
- 4a. Are you currently pregnant?
- 4b. How many weeks? weeks Don't Know

At the bottom of the screen, there is a navigation bar with buttons for "End of Section", "Close Exam", and "Finish". A blue arrow button is located in the bottom right corner.

- Press the arrow button to advance to the next screen.

If the blood pressure component has been completed in the Physician Exam, the screens for blood pressure measurement will not appear and the status screen will be displayed with the section set to complete.

Exhibit 4-2. Blood Pressure Section Status from Physician

Cardiovascular Fitness: Stand:410 Session:410791 11/05/2004 01:30 pm - 05:30 pm

SP ID: 171464 Name: SMITH, ASHLEE Age: 21 years Gender: Female Date: 12/23/2004 Time: 01:18 PM

Blood Pressure Status

Status

Complete
 Partial
 Not Done

Comments

Other text

9 of 9

End of Section Close Exam Finish

- Press the arrow button to advance to the next screen. See Exhibit 4-2 above.

4.2. Height and Weight Measurements to Determine BMI

The Integrated Survey Information System (ISIS) is the data entry system that is used in this study. See Section 1.3 for a brief description of ISIS. Detailed procedures for conducting the treadmill test are outlined in Chapter 3. The purpose of this chapter is to provide a step-by-step guideline on the data entry for this component.

Exhibit 4-3. Weight and height measurements from body composition



The screenshot displays a software window titled "Cardiovascular Fitness: Stand:107 Session:107012 07/06/1999 05:30 pm - 09:30 pm". The window contains a header bar with the following information: "SP ID: 818591 Name: BROWN, MAC Age: 38 years Gender: Male Date: 10/10/2000 Time: 12:46 PM". Below the header, the section is titled "SP Height and Weight Information". The main area of the window shows two input fields: "Measured Weight: 77.1 Kgs" and "Measured Height: 170. Cms". At the bottom of the window, there is a navigation bar with buttons for "End of Section", "Close Exam", and "Finish", along with a blue arrow icon.

- As soon as you bring the SP into the CV Fitness room you should log onto the system. Then wand the SP into the system to confirm that you are conducting the test on the correct SP.
- Do not start the height and weight measurements until you have logged onto the system.
- If the SP completed the Body Measures component prior to starting the CV Fitness component, the height and weight measurements from that component will be pulled from the database and displayed on the first screen. The fields for weight and height measurements will be disabled to prevent unnecessary entry. See Exhibit 4-3 above.

Exhibit 4-4. Weight and height measurements in CV Fitness room

Cardiovascular Fitness: Stand:107 Session:107012 07/06/1999 05:30 pm - 09:30 pm

SP ID: 818591 Name: BROWN, MAC Age: 38 years Gender: Male Date: 10/10/2000 Time: 12:48 PM

SP Height and Weight Information

Measured Weight: 77.1 Kgs

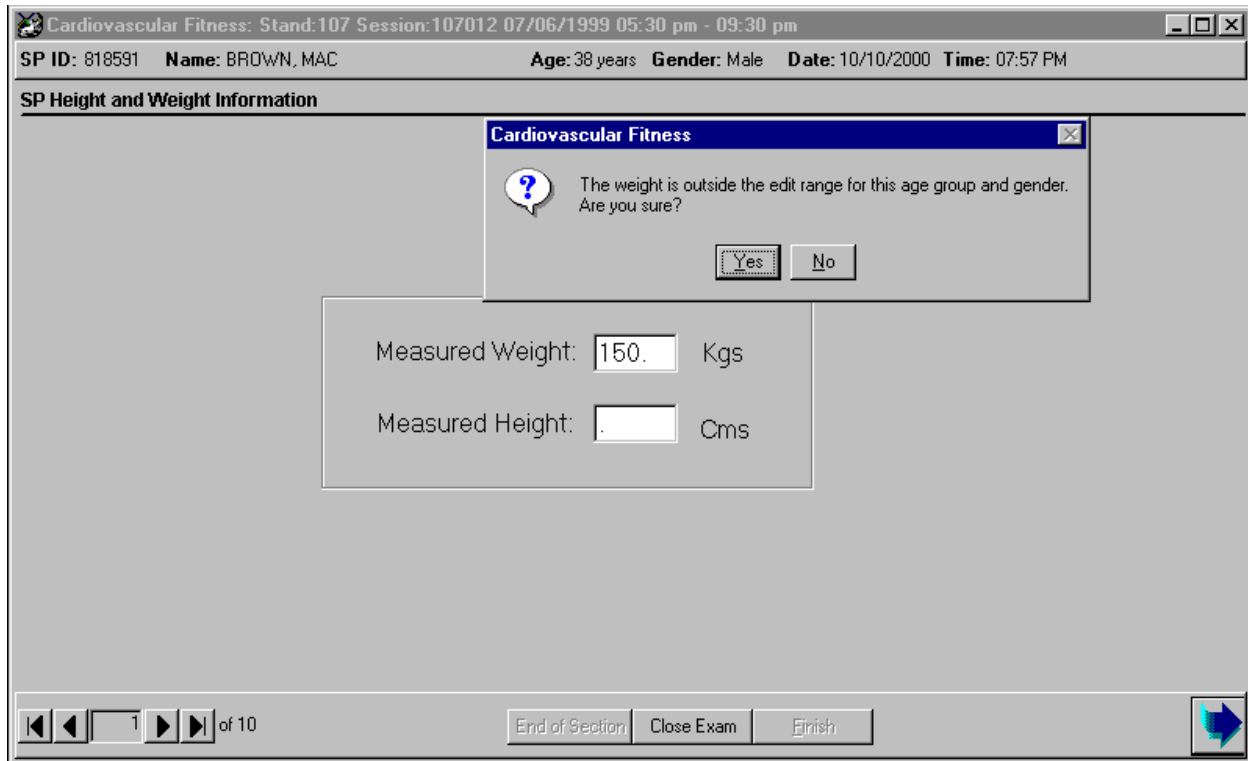
Measured Height: 170. Cms

1 of 10 End of Section Close Exam Finish

- If the SP didn't complete the body measures component prior to entering the CV Fitness component, the weight and height will have to be measured in the CV Fitness room. The SP should not be wearing his or her shoes for either measurement.
- First, measure the SP's weight using the floor scales. Enter the weight in kilograms in the weight field.
- Next, measure the SP's height using the stadiometer. Enter the height in centimeters in the height field.
- The height and weight measurements will be used to determine Body Mass Index (BMI) which in turn will be used in the calculation of the VO_2 max.

4.2.1 Edits on Data Entry for Weight and Height

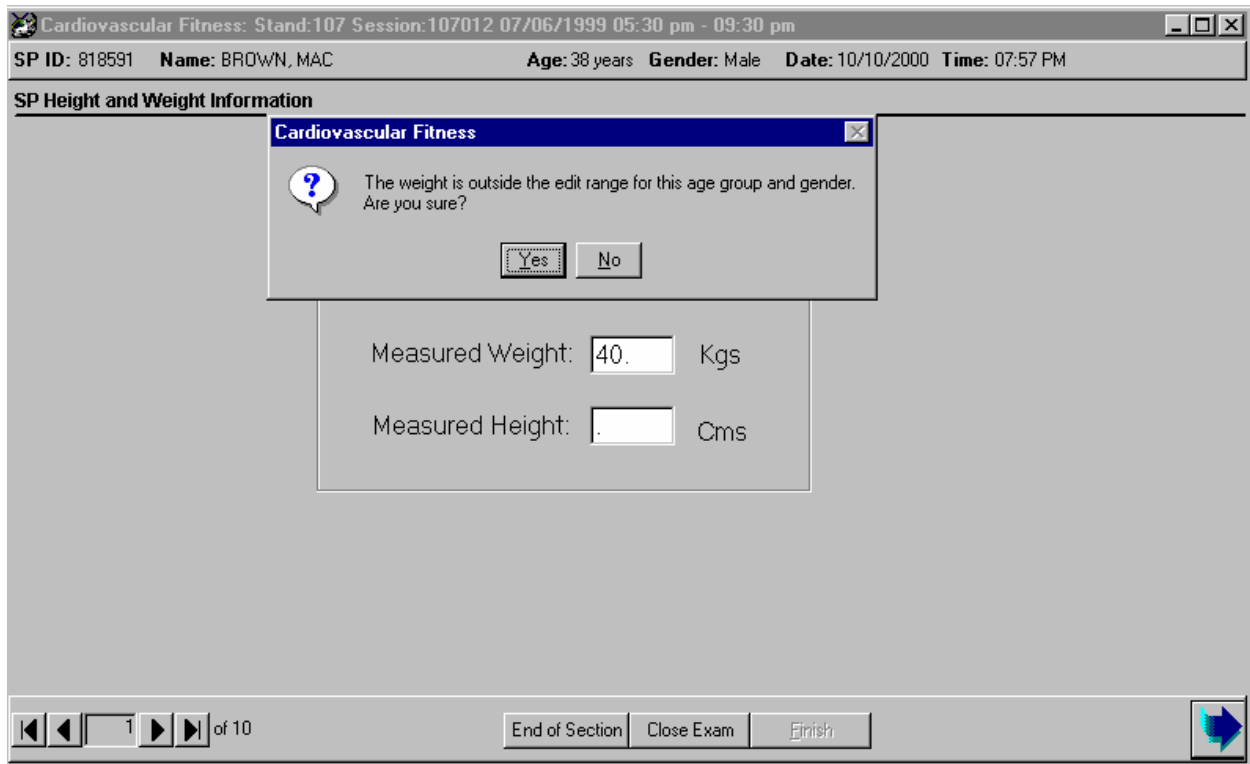
Exhibit 4-5. Edit message on incorrect data entry for weight



The height and weight fields have set edit limits based on the 1999 NHANES data.

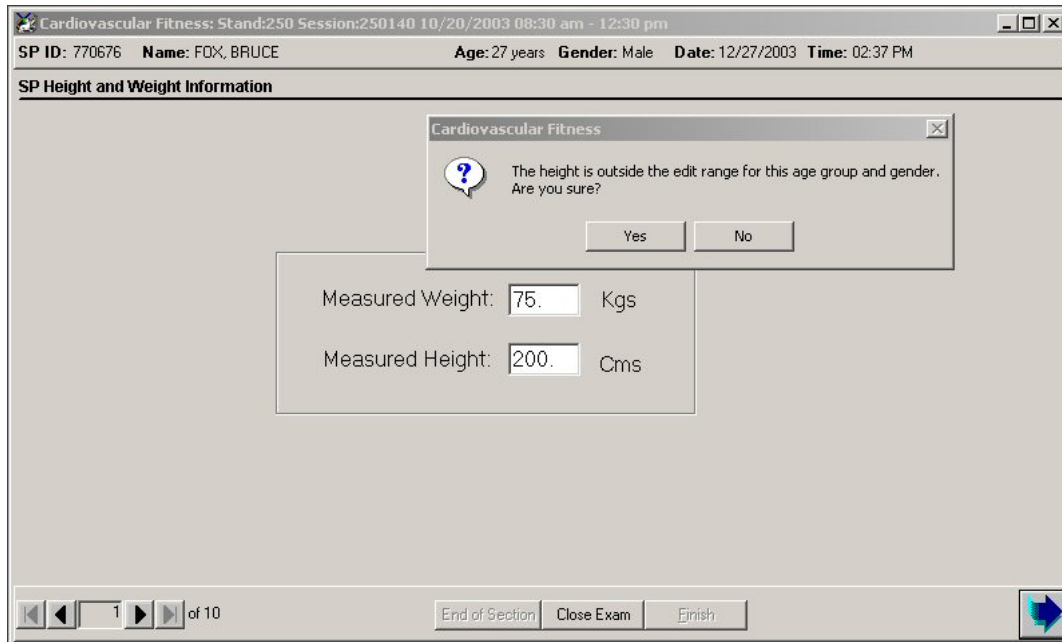
- If the weight entered is outside the edit limits, the ISIS system will display a message: "The weight is outside the edit range for this age group and gender. Are you sure?"
- If the weight you entered is correct, select 'yes.' If the data was entered incorrectly, select 'no' and re-enter the correct value for weight.

Exhibit 4-6. Edit message on incorrect data entry for weight (below edit range)



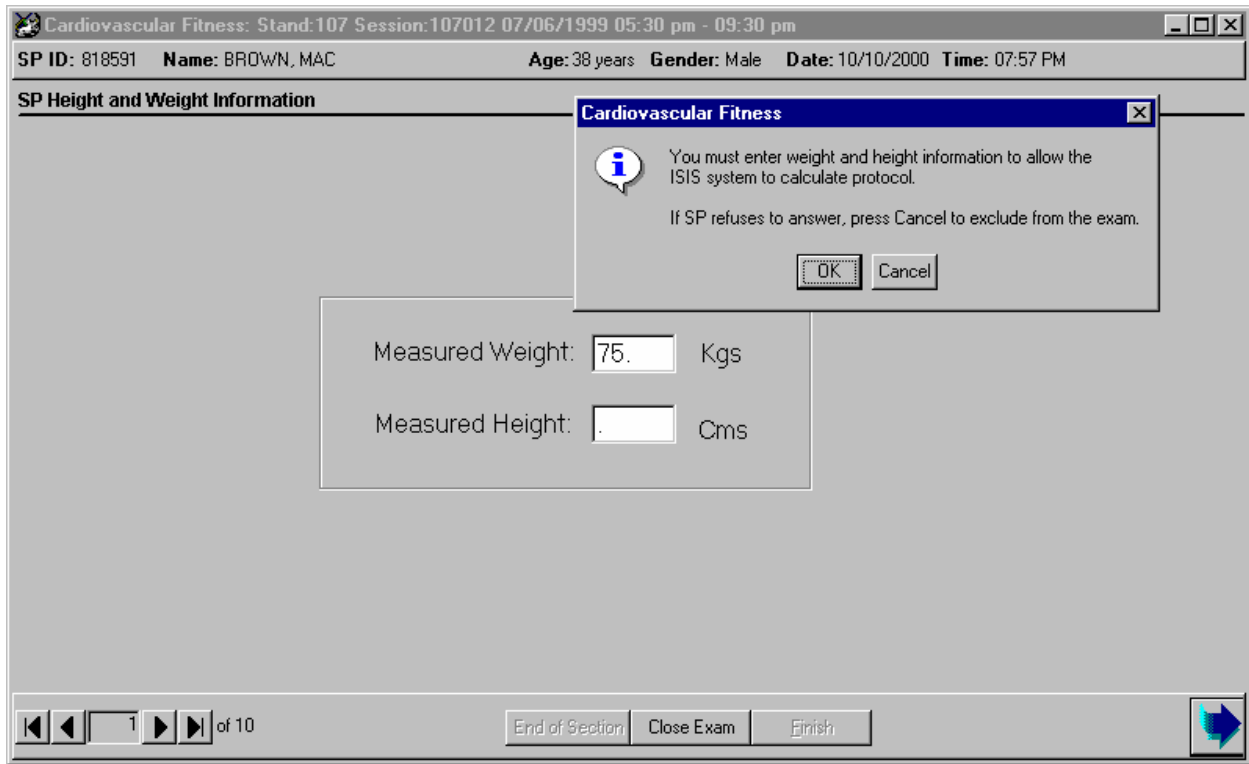
- If the weight entered is below the edit limits, the ISIS system will display a message: "The weight is outside the edit range for this age group and gender. Are you sure?"
- If the weight you entered is correct, select 'yes.' If the data was entered incorrectly, select 'no' and re-enter the correct value for weight.

Exhibit 4-7. Edit message on incorrect data entry for height



- If the height entered is outside the edit limits, the ISIS system will display a message: “The weight is outside the edit range for this age group and gender. Are you sure?”
- If the height you entered is correct, select ‘yes.’ If the data was entered incorrectly, select ‘no’ and re-enter the correct value for weight.

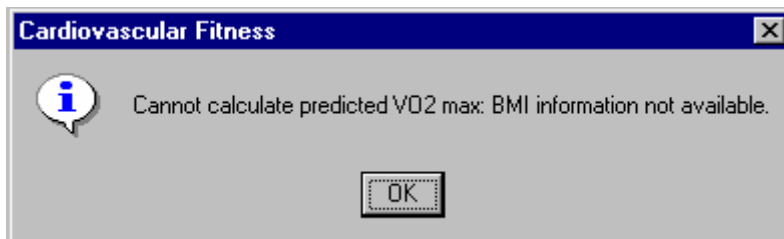
Exhibit 4-8. Required data entry for height and weight



- If the height and/or weight are not entered and the Next button is pressed, the ISIS system will display a message 'You must enter weight and height information to allow the ISIS system to calculate protocol. Press OK to continue to enter the weight and height information.

If SP refuses to answer or you cannot obtain the height and weight for some other reason such as equipment problems, press the Cancel button to exclude the SP from the exam.

Exhibit 4-9. Cannot calculate VO₂ max



- If the Cancel button is selected, the SP will be excluded. The ISIS system will display a message to indicate that the predicted VO₂ max cannot be calculated if the BMI information is not available. Click OK to this message.

Exhibit 4-10. Partial status with comment 'Other, specify'

Cardiovascular Fitness: Stand:107 Session:107401 08/14/1999 01:30 pm - 05:30 pm

SP ID: 531764 Name: ELLA, CINDER Age: 25 years Gender: Female Date: 07/04/2000 Time: 08:46 AM

Cardiovascular Fitness Component Status

Status

Complete

Partial

Not Done

Comments other, specify

Other text Unable to get ht & wt information - SP refused

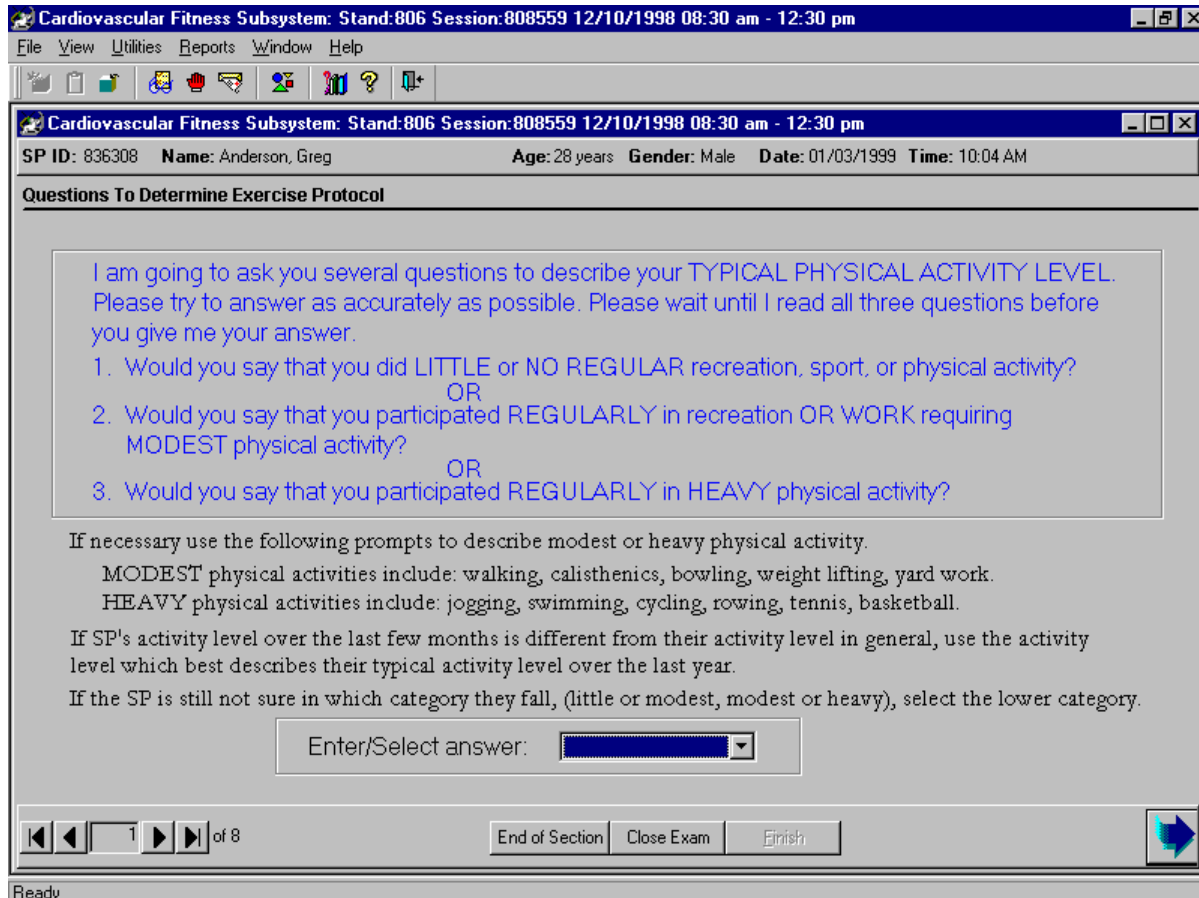
9 of 9

End of Section Close Exam Finish

- The ISIS system will go to the Component Status screen and the Status will be set to Partial.
- If the reason the BMI could not be calculated was due to SP refusal to have weight and height measured, select 'Other, specify' for comments and enter 'Unable to get ht and wt information - SP refusal' in the 'Other text' field.
- If the reason the BMI could not be calculated was another reason, enter the appropriate information in the 'Other text' field.

4.3 Questions to Determine Exercise Protocol (PAR Code Questions)

Exhibit 4-11. Questions to determine protocol

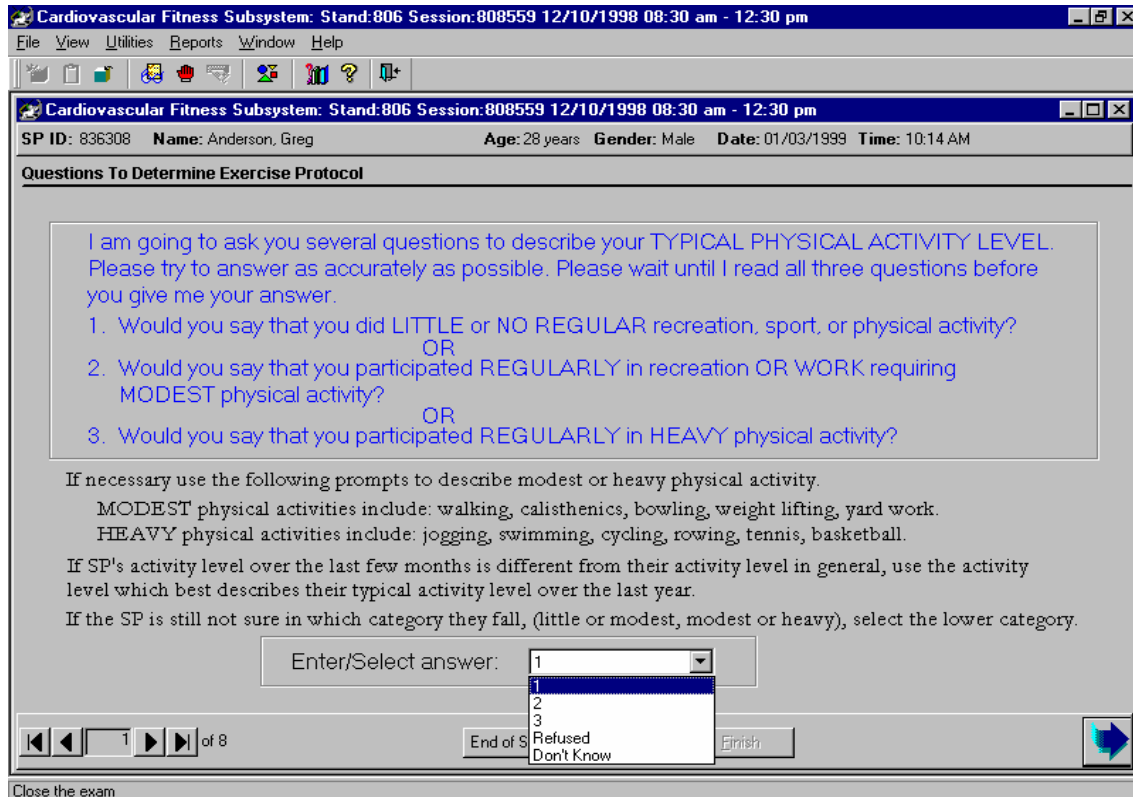


- The questions on the next few screens are designed to determine the exercise protocol that will be assigned to the SP.
- These questions are based on the Physical Activity Readiness (PAR) Questionnaire and will be used to determine a PAR Code that is used to calculate the predicted VO_2 max.
- The predicted VO_2 max is used to determine the exercise protocol for each individual SP. See Appendix F for more details.
- Exhibit 4-11 shows the first level questions used to determine the SP's regular physical activity level. These questions should be read exactly as written.
- If the SP interrupts and gives an answer before you have completed asking the question, tell the SP that you are required to read the entire set of options before you accept a response.

- Read the options clearly and slowly enough for the SP to understand what the options are. Put special emphasis on the words in capital letters.
- If the SP is not sure about the difference between heavy and modest activities, use the examples listed for these activities.
- If the SP's activity level over the last few months is different from his or her activity level in general, use the activity level which best describes the activity level over the last year.
- If the SP is still not sure in which category they fall, (little or modest, modest, or heavy), select the lower category.
- Encourage the SP to answer as honestly as possible to obtain the exercise protocol that will get valid information about their fitness level.
- Select 1, 2, or 3 from the drop-down menu.
- If the SP refuses to answer or is unable to give an answer, select Refused or Don't Know. If 'Refused' or 'Don't Know' are selected, the SP will be excluded from the exam.
- When the Next button is pressed, the ISIS system will go to the Component Status Screen. The Status will be set to 'Not Done' with the comment 'Unable to calculate protocol.'

4.3.1 First Level Questions

Exhibit 4-12. First level questions to determine exercise protocol



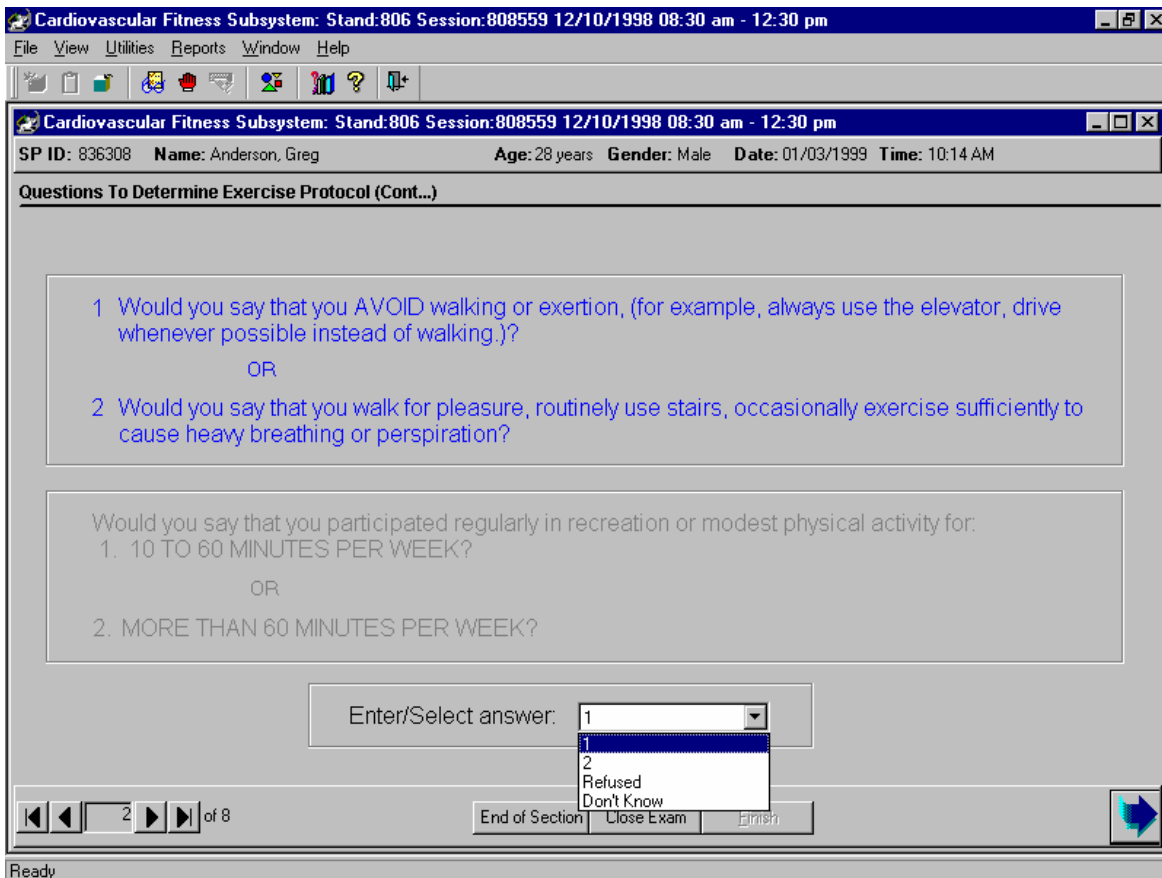
Little or no recreation, sport, or physical activity: If the SP is not regularly involved in recreation, sport, or physical activity, select 1 from the drop-down menu. If #1 (little or no regular physical activity) is selected from the first level activity questions in Exhibit 4-12 above, the ISIS system will advance to the screen for the second level activity questions for ‘little or no regular physical activity.’ See Exhibit 4-13.

Regular modest physical activity: If the SP participates regularly in modest physical activity from recreation or work, select 2 from the drop down menu. The activity should be typical physical activity and should be done on a regular basis rather than sporadically or in an earlier time period. Emphasize the words in capital letters when reading the choices. If #2 (regular, modest physical activity) is selected from the first level activity questions in Exhibit 4-12 above, the ISIS system will advance to the screen for the second level activity questions for ‘regular modest physical activity.’ See Exhibit 4-14.

Heavy physical activity: If #3 (regular, heavy physical activity) is selected from the first level activity questions in Exhibit 4-12 above, the ISIS system will advance to the screen for the second level activity questions for ‘regular, heavy physical activity.’ See Exhibit 4-15 on page 4-16.

4.3.2 Second Level Questions (Little or No Regular Physical Activity)

Exhibit 4-13. Little or no regular physical activity (second level questions)



- If 1 is selected from the first level activity questions (see Exhibit 4-12 shown earlier), the ISIS system will advance to the second level activity questions for ‘little or no regular activity.’ The second level questions for this category will be highlighted.
- Read both highlighted options entirely before accepting the SP’s response. As with the previous options, if the SP interrupts with an answer before you have completed reading the options, remind them that you are required to read the options entirely before accepting their response.

- These questions are used to determine if the SP avoids walking or exertion such as always using an elevator or driving whenever possible instead of walking. The other option is if he or she walks for pleasure, routinely uses stairs, or occasionally exercises sufficiently to cause heavy breathing or perspiration.
- If the SP is having difficulty choosing between the options, read the options again to give them time to decide. Do not answer the question for the SP. Ask him or her to choose the option that is closest to their usual activity level. If the SP refuses to select an answer or is unable to give a response, select 'Refused' or 'Don't Know' from the drop-down menu. If 'Refused' or 'Don't Know' is selected, the SP is excluded.
- The ISIS system will go to the Component Status screen. The status will be set to 'Not Done' with the comment 'Unable to calculate protocol.' Most SP's will be able to select one of the options. Select 1 or 2 from the drop-down menu. Press the Next button to advance to the next screen.

4.3.3 Second Level Questions (Regular Modest Physical Activity)

Exhibit 4-14. Regular modest physical activity (second level questions)

Cardiovascular Fitness Subsystem: Stand:806 Session:808559 12/10/1998 08:30 am - 12:30 pm

SP ID: 836308 Name: Anderson, Greg Age: 28 years Gender: Male Date: 01/03/1999 Time: 10:14 AM

Questions To Determine Exercise Protocol (Cont...)

1 Would you say that you AVOID walking or exertion, (for example, always use the elevator, drive whenever possible instead of walking.)?
OR
2 Would you say that you walk for pleasure, routinely use stairs, occasionally exercise sufficiently to cause heavy breathing or perspiration?

Would you say that you participated regularly in recreation or modest physical activity for:
1. 10 TO 60 MINUTES PER WEEK?
OR
2. MORE THAN 60 MINUTES PER WEEK?

Enter/Select answer:

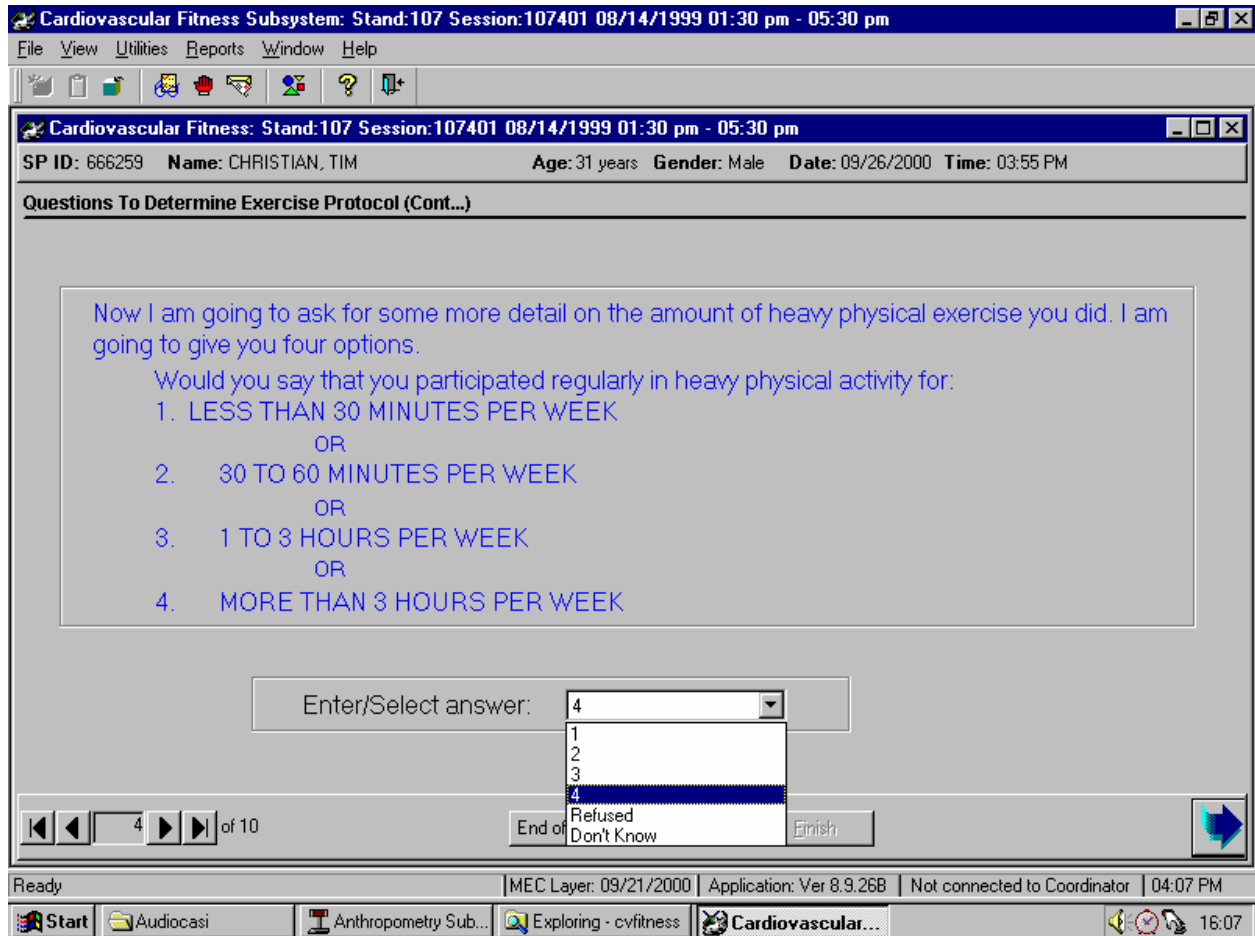
2 of 8

End of Section Close Exam Finish

- If 2 is selected from the first level activity questions (see Exhibit 4-12 shown earlier), the ISIS system will advance to the second level activity questions for regular, modest activity. The second level questions for this category will be highlighted.
- Read both highlighted options entirely before accepting the SP's response. As with the previous options, if the SP interrupts with an answer before you have completed reading the options, remind them that you are required to read the options entirely before accepting their response.
- These questions are used to determine the amount of time the SP spends in regular, modest physical activity per week.
- If they spend 10 to 60 minutes per week in regular, modest physical activity, select 1 from the drop-down menu.
- If they spend more than 60 minutes per week in regular, modest physical activity, select 2 from the drop-down menu.
- If the SP is having difficulty choosing between the options, read the options again to give them time to decide. Do not answer the question for them. Ask them to choose the option that is closest to their usual activity level.
- If the SP refuses to select an answer or is unable to give a response, select 'Refused' or 'Don't Know' from the drop-down menu. If 'Refused' or 'Don't Know' is selected, the SP is excluded.
- The ISIS system will go to the Component Status screen. The status will be set to 'Not Done' with the comment 'Unable to calculate protocol.' Most SP's will be able to select one of the options. Select 1 or 2 from the drop-down menu. Press the Next button to advance to the next screen.

4.3.4 Second Level Questions (Regular Heavy Physical Activity)

Exhibit 4-15. Second level questions (regular heavy physical activity)

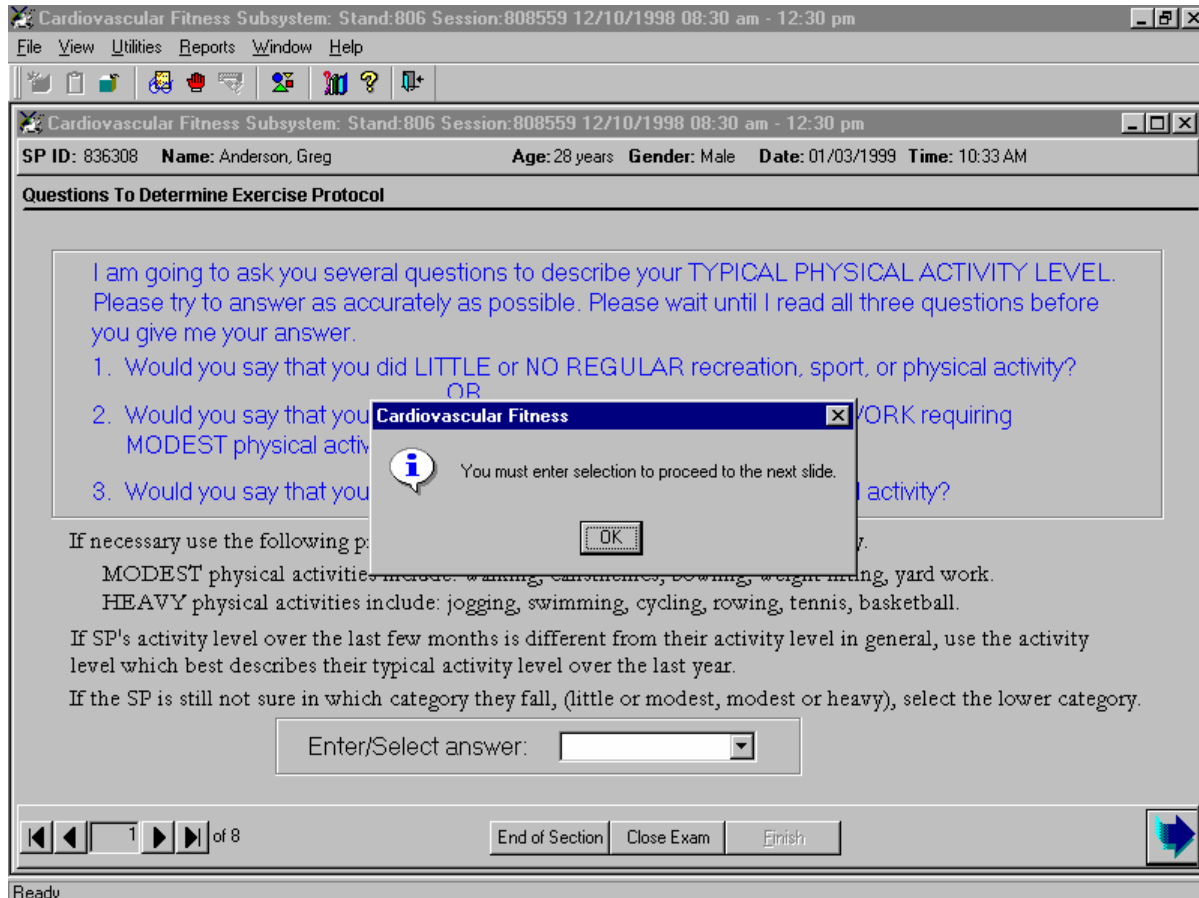


- If 3 is selected from the first level activity questions (see Exhibit 4-12 shown earlier), the ISIS system will advance to the second level questions for regular, heavy physical activity.
- The second level questions for regular, heavy physical activity have four options to determine the amount of time per week spent in this type of activity.
- These options are used to determine the amount or degree of regular, heavy physical activity the SP does.
- Read all four highlighted options before accepting the SP's response. Read the options carefully and slowly enough for the SP to understand the time period associated with each response.
- If they spend less than 30 minutes/week in regular, heavy physical activity, select 1.

- If they spend 30-60 minutes per week in regular, heavy physical activity, select 2.
- If they spend 1-3 hours per week in regular, heavy physical activity, select 3.
- If they spend more than 3 hours per week in regular, heavy physical activity, select 4.
- If the SP is having difficulty choosing between the options, read the options again to give them time to decide. Do not answer the question for them. Ask them to choose the option that is closest to their usual activity level.
- If the SP refuses to select an answer or is unable to give a response, select 'Refused' or 'Don't Know' from the drop-down menu. If 'Refused' or 'Don't Know' is selected, the SP is excluded. The ISIS system will go to the Component Status screen. The status will be set to 'Not Done' with the comment 'Unable to calculate protocol.' Most SP's will be able to select one of the options. Select 1, 2, 3, or 4 from the drop-down menu.

4.3.5 Required Data Entry for PAR Questions

Exhibit 4-16. Required data entry for first level activity questions



- If a response is not selected for the physical activity questions and the Next button is pressed, the ISIS system will display a reminder message 'You must enter selection to proceed to the next slide.'
- Click OK and enter the response.
- Press the Next button to advance to the next screen.

4.4 Pretest Measurements

Exhibit 4-17. Pretest measurements

The screenshot shows a software window titled "Cardiovascular Fitness: Stand:703 Session:703360 04/09/1999 08:30 am - 12:30 pm". The patient information at the top includes "SP ID: 618864", "Name: PARKER, JACK", "Age: 21 years", "Gender: Male", "Date: 08/14/1999", and "Time: 07:15 AM". The main section is titled "Pretest Measurements" and contains the following fields and controls:

- Room Temperature: Degrees
- Exam Preparation** section:
 - Arm:
 - Cuff Size:
 - Mesh Vest Used:
- Pretest Measurements** section:
 - Heart Rate:
 - Systolic BP:
 - Diastolic BP:
 -

At the bottom, there are navigation controls: a set of arrows with "4 of 9" in the middle, and three buttons: "End of Section", "Close Exam", and "Einish". A blue arrow icon is also present in the bottom right corner.

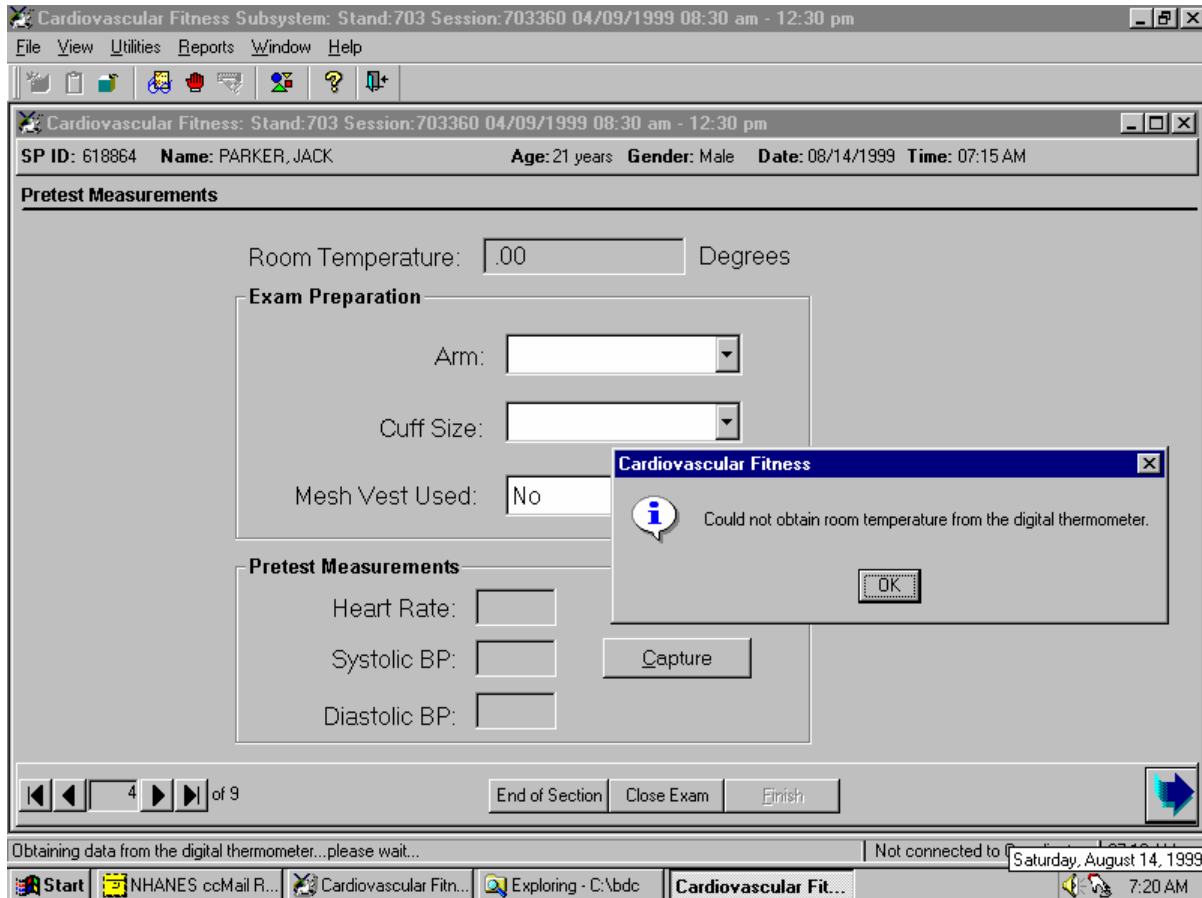
- A digital thermometer is directly integrated with the ISIS system. The system will capture the room temperature and display it on the screen. The system will then give an auditory message:

“Check footwear, attach chest electrodes and BP cuff. Then explain treadmill test.”

- The initial footwear check is done as soon as the SP comes in the room. This is another reminder to check the footwear again for proper type and to make sure laces are tied if appropriate. If the footwear is not appropriate, get the shoe size and give the SP a pair of running shoes from the stock supply. (See Section 2.6.2 for discussion of appropriate footwear and Section 3.4 for discussion of checking footwear prior to the test.)
- Attach the chest electrodes and blood pressure cuff. (See Section 3.8.1 to 3.8.3 for discussion of proper placement of electrodes and cuff.) If the SP's chest hair interferes with the attachment of the electrodes, do not shave the site to avoid unintended injury or discomfort to the SP. If the SP has chest hair that makes the adherence of the electrodes on the chest difficult, ask the SP to put on a mesh vest that will assist in keeping the electrodes attached. If the mesh vest is used, check 'yes' to Mesh Vest. This field is defaulted to 'No' and is disabled for females. See Section 3.8.5.

4.4.1 Digital Thermometer for Measuring Room Temperature

Exhibit 4-18. Unable to obtain room temperature



- If the digital room thermometer does not capture the room temperature, the ISIS system will display a message: ‘Could not obtain room temperature from the digital thermometer.’
- Click OK.
- Check the room temperature on the digital display and type in the temperature in the appropriate field on the screen.

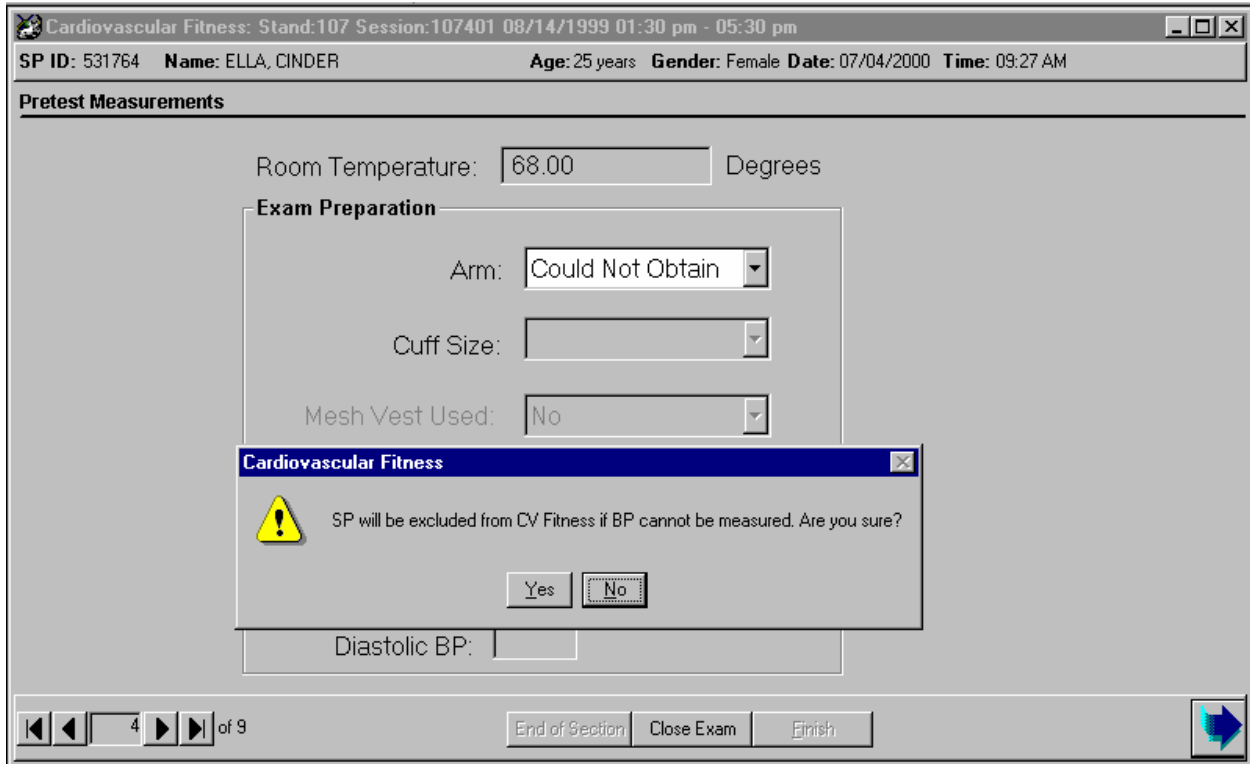
4.4.2 Exam Preparation –Arm Used, Cuff Size, Mesh Vest Used

Exhibit 4-19. Exam preparation – arm selected

The screenshot displays the 'Cardiovascular Fitness Subsystem' software interface. The title bar indicates 'Stand:107 Session:107401 08/14/1999 01:30 pm - 05:30 pm'. The main window shows patient information: 'SP ID: 934124 Name: THORNTON, JOHN Age: 25 years Gender: Male Date: 07/08/2000 Time: 01:03 PM'. Under the 'Pretest Measurements' section, the 'Room Temperature' is set to 68.00 Degrees. The 'Exam Preparation' section includes three dropdown menus: 'Arm' (set to 'Right'), 'Cuff Size' (set to 'Left'), and 'Mesh Vest Used' (set to 'No'). Below this, there are input fields for 'Heart Rate', 'Systolic BP', and 'Diastolic BP', along with a 'Capture' button. The bottom of the window features navigation controls, including 'End of Section', 'Close Exam', and 'Finish' buttons. The Windows taskbar at the bottom shows the system is 'Ready', 'Not connected to Coordinator', and the time is '01:25 PM'.

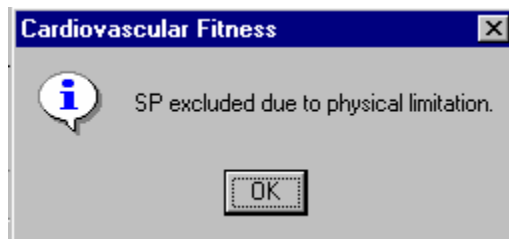
- Select the arm used for blood pressure measurements from the drop-down menu. The options are right, left, and could not obtain.
- The right arm will be used for all BP measurements unless there is a reason for not using this arm. See Section 3.8.2 for discussion of selection of arm to use for blood pressure measurement.

Exhibit 4-20. SP excluded if neither arm can be used for BP measurement



- If you are unable to put a cuff on either arm, select 'could not obtain.' If the blood pressure could not be monitored, the SP will be excluded due to physical limitation.
- The ISIS system will display a message 'SP will be excluded from CV Fitness if BP cannot be measured. Are you sure?' Select Yes if this is true.

Exhibit 4-21. SP excluded due to physical limitation



- If Yes is selected, the ISIS system will display a message: "The SP will be excluded due to physical limitation." Select OK.
- The Component Status screen will be displayed.

Exhibit 4-22. Partial status with physical limitation if CNO selected for arm

Cardiovascular Fitness: Stand:990 Session:990300 10/05/1999 08:30 am - 12:30 pm

SP ID: 427581 Name: DONOHUE, MAURIE Age: 23 years Gender: Female Date: 07/12/2000 Time: 03:33 PM

Cardiovascular Fitness Component Status

Status

Complete

Partial

Not Done

Comments physical limitation

Other text

9 of 9

End of Section Close Exam Finish

- If you selected 'Could Not Obtain' for arm used, the Status will be set to 'Partial' with the comment 'physical limitation.'
- Press the Finish button to end the exam.

Exhibit 4-23. Selection of cuff size

Cardiovascular Fitness Subsystem: Stand:990 Session:990300 10/05/1999 08:30 am - 12:30 pm

File View Utilities Reports Window Help

Cardiovascular Fitness: Stand:990 Session:990300 10/05/1999 08:30 am - 12:30 pm

SP ID: 427581 Name: DONOHUE, MAURIE Age: 23 years Gender: Female Date: 07/11/2000 Time: 05:43 PM

Pretest Measurements

Room Temperature: Degrees

Exam Preparation

Arm:

Cuff Size:
child
adult
large arm

Mesh Vest Used:

Pretest Measurements

Heart Rate:

Systolic BP:

Diastolic BP:

4 of 9

Ready | Not connected to Coordinator | 05:52 PM

- Select the cuff size used from the ‘Cuff size’ drop-down menu. The sizes are ‘child,’ ‘adult,’ and ‘large arm.’
- Most problems with cuff placement will be a problem with the arm rather than the cuff and ‘Could not obtain’ should be selected for arm as described above. There may be some situations where the arm can be used but for some reason the cuff cannot be positioned as described in Section 3.8.3. Make every effort to attempt to position the cuff correctly before deciding to exclude the SP for this reason.
- If you are unable to position a cuff correctly on the SP’s arm, the SP will be excluded.
- Press the ‘Close Exam’ button at the bottom of the screen. The status screen will be displayed.

Exhibit 4-24. Problem with cuff size

Cardiovascular Fitness: Stand:107 Session:107401 08/14/1999 01:30 pm - 05:30 pm
SP ID: 531764 Name: ELLA, CINDER Age: 25 years Gender: Female Date: 07/04/2000 Time: 09:27 AM

Pretest Measurements

Room Temperature: 68.00 Degrees

Exam Preparation

Arm: Right

Cuff Size:

Mesh Vest Used:

Pretest Measurements

Heart Rate:

Systolic BP:

Diastolic BP:

Cardiovascular Fitness

SP ID:531764 SP Name:ELLA, CINDER

Exam Status: partial

Comments: Problem with BP cuff

Other text:

This will close the exam, saving all results and the exam status.
Do you wish to close the exam?

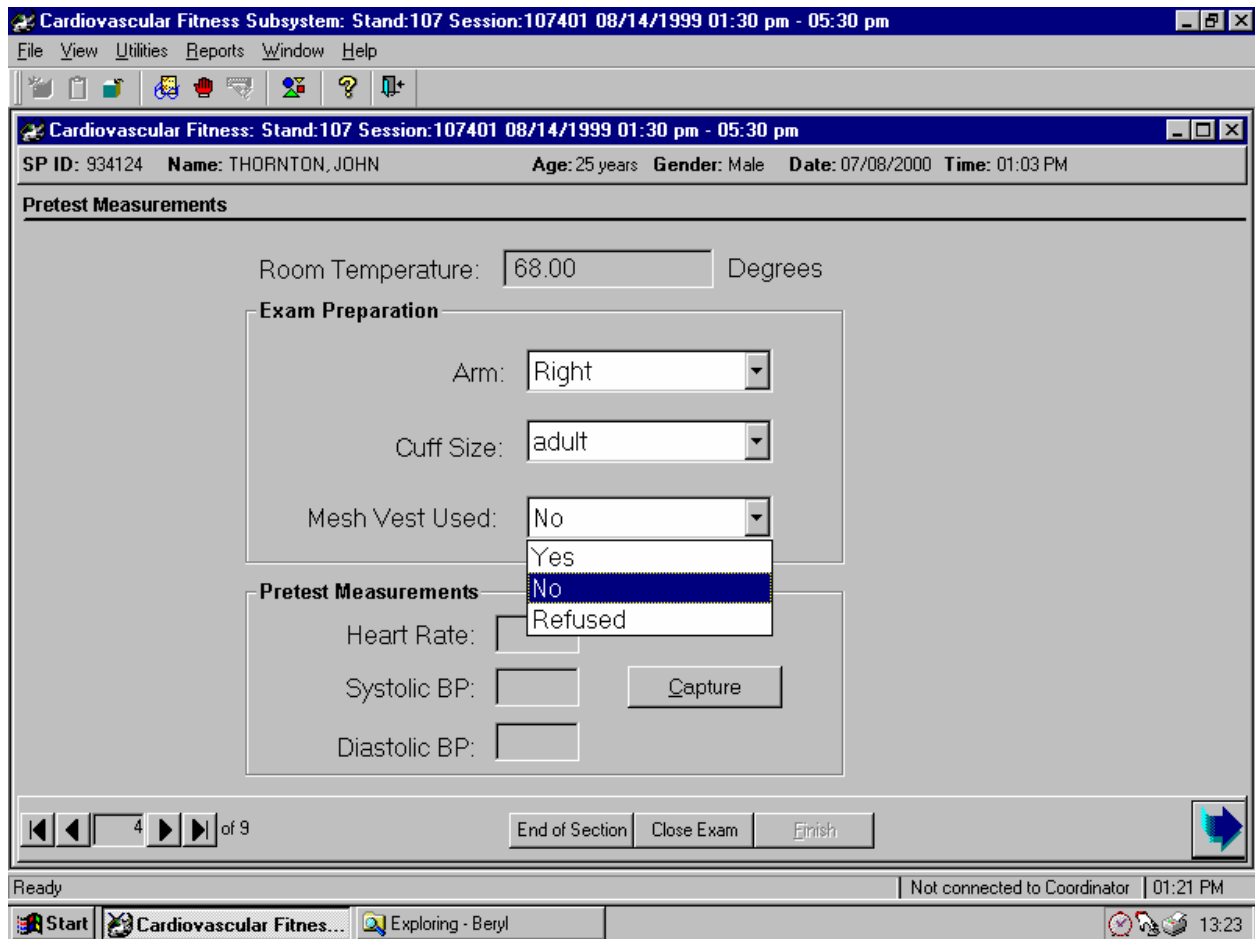
OK Cancel

4 of 9

End of Section Close Exam Finish

- Select 'Close Exam' and the Status screen will be displayed.
- Select 'Problems with BP cuff' or "Other, specify" and enter the reason in the 'Other text' field.
- Select OK to close the exam.

Exhibit 4-25. Mesh vest used



- If the SP is male, the field for Mesh Vest Used will be enabled. A mesh vest is used to optimize adherence of the chest electrodes in men with a large amount of chest hair. See Section 3.8.5.
- Select Yes or No from the drop-down menu.
- If the SP is female, this field will be disabled.

4.4.3 Capturing Blood Pressure Measurements

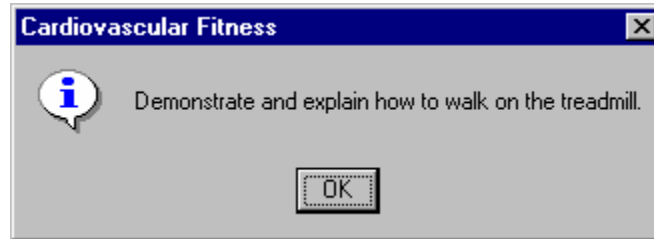
Exhibit 4-26. Blood pressure data capture

The screenshot shows a software window titled "Cardiovascular Fitness: Stand:703 Session:703360 04/09/1999 08:30 am - 12:30 pm". The window contains a form for "Pretest Measurements". At the top, it displays "SP ID: 618864 Name: PARKER, JACK Age: 21 years Gender: Male Date: 08/14/1999 Time: 07:15 AM". Below this, the "Pretest Measurements" section includes a "Room Temperature" field set to "68.00" Degrees. An "Exam Preparation" box contains three dropdown menus: "Arm" set to "Right", "Cuff Size" set to "adult", and "Mesh Vest Used" set to "No". A second "Pretest Measurements" box contains three input fields: "Heart Rate" set to "60", "Systolic BP" set to "118", and "Diastolic BP" set to "78". A "Capture" button is positioned to the right of the Systolic BP field. At the bottom of the window, there are navigation controls including a "4 of 9" indicator, "End of Section", "Close Exam", and "Finish" buttons, along with a blue arrow icon.

- When the cuff is attached to the arm, ask the SP to relax his or her arm by the side.
- Press the 'Capture' button to initiate the blood pressure readings.
- The ISIS system will initiate the blood pressure measurement and capture the reading.
- The readings will be displayed on the screen.
- Prior to starting the treadmill test, give a brief demonstration of how to walk on a treadmill. (See Section 3.9.5 for details).

4.4.4 Demonstrating and Explaining How to Walk on a Treadmill

Exhibit 4-27. Demonstrate and explain how to walk on a treadmill



- When the heart rate and blood data are captured, the ISIS system displays a second visual message: ‘Demonstrate and explain how to walk on a treadmill.’
- Press “Start Belt” and increase the speed of the treadmill to 2.0 mph.
- Explain the procedures step-by-step as you demonstrate.
- Straddle the belt and hold onto the handrail with both hands.
- Tell them to ‘paw’ the belt with one foot to get a feel for the movement of the belt and then step on the treadmill and begin to walk.
- Place emphasis on the importance of an upright posture, looking straight ahead nor down at the feet, and taking long steps with a relaxed gait. Drop one arm by the side and then the other one.
- Step off the belt and press Stop Belt on treadmill controller. Press Clear on treadmill controller.
- Press OK to the message on ISIS screen.
- Advance to the treadmill test screen after you have given the demonstration.

4.4.5 Required Data Entry for Arm and Cuff Size

Exhibit 4-28. Required data entry for arm and cuff used

The screenshot displays the 'Cardiovascular Fitness Subsystem' software interface. The window title is 'Cardiovascular Fitness Subsystem: Stand:703 Session:703360 04/09/1999 08:30 am - 12:30 pm'. The menu bar includes 'File', 'View', 'Utilities', 'Reports', 'Window', and 'Help'. The main window shows patient information: 'SP ID: 618864', 'Name: PARKER, JACK', 'Age: 21 years', 'Gender: Male', 'Date: 08/14/1999', and 'Time: 07:15 AM'. The 'Pretest Measurements' section contains the following fields: 'Room Temperature: 68.00 Degrees', 'Exam Preparation' (a sub-section containing 'Arm:' and 'Cuff Size:' dropdown menus), and 'Mesh Vest Used: No'. Below this, another 'Pretest Measurements' section contains 'Heart Rate: 60', 'Systolic BP: 118', and 'Diastolic BP: 78'. A 'Capture' button is located between the two measurement sections. A modal dialog box titled 'Cardiovascular Fitness' is overlaid on the screen, displaying an information icon and the message: 'You must select arm and cuff size to proceed to the next slide.' with an 'OK' button. The bottom of the window features navigation buttons: 'End of Section', 'Close Exam', and 'Finish'. The Windows taskbar at the bottom shows the system tray with 'Ready', 'Not connected to Coordinator', and '07:24 AM'. The taskbar also displays the Start button and several open applications: 'NHANES ccMail Router', 'Cardiovascular Fitness...', and 'Exploring - C:\bdc'.

- You cannot advance to the next screen if all the data fields are not complete.
- If you do not select the arm or cuff size used, the ISIS system will display a message: ‘You must select arm and cuff size to proceed to the next slide.’
- Click OK.
- Select arm and cuff size.

4.4.6 Required Data Entry for BP Measurements

Exhibit 4-29. Required data entry for blood pressure

The screenshot displays the 'Cardiovascular Fitness' software interface. At the top, the window title is 'Cardiovascular Fitness: Stand:990 Session:990300 10/05/1999 08:30 am - 12:30 pm'. Below this, patient information is shown: 'SP ID: 427581 Name: DONOHUE, MAURIE Age: 23 years Gender: Female Date: 07/11/2000 Time: 05:43 PM'. The main section is titled 'Pretest Measurements'. It includes a 'Room Temperature' field with the value '68.00' and the unit 'Degrees'. Below this is an 'Exam Preparation' section with three dropdown menus: 'Arm:' set to 'Right', 'Cuff Size:' set to 'adult', and 'Mesh Vest Used:' set to 'No'. Underneath is another 'Pretest Measurements' section with three input fields for 'Heart Rate:', 'Systolic BP:', and 'Diastolic BP:'. A 'Capture' button is positioned to the right of the Systolic BP field. A small dialog box titled 'Cardiovascular Fitness' is overlaid on the right side of the main window, containing an information icon, the text 'Obtain Pretest BP Measurements.', and an 'OK' button. At the bottom of the main window, there are navigation buttons: 'End of Section', 'Close Exam', and 'Finish', along with a blue arrow button on the far right. A status bar at the bottom left shows '4 of 9'.

- See Section 3.9.1 for setup of blood pressure monitor. If the Next button is pressed before the blood pressure data is captured, the ISIS system will display a message: ‘Obtain Pretest BP measurements.’
- Click OK.
- Click on the ‘Capture’ button to obtain the blood pressure readings.

4.5 Treadmill Test

Exhibit 4-30. Treadmill test data entry screen

Cardiovascular Fitness: Stand:250 Session:250140 10/20/2003 08:30 am - 12:30 pm

SP ID: 770676 Name: FOX, BRUCE Age: 27 years Gender: Male Date: 12/27/2003 Time: 02:37 PM

Treadmill Test

00:00
min sec

START

RESTART

EMERGENCY STOP

Change Protocol

Go To Recovery

Show Data

Vo2 Max: .00

Protocol	WARM-UP		STAGE 1		STAGE 2		RECOVERY	
	Speed	Grade	Speed	Grade	Speed	Grade	Speed	Grade
5	3.00	3.00	3.70	4.00	3.70	8.00	2.00	0
6	3.10	3.50	3.70	5.50	3.70	10.0	2.00	0
7	3.20	5.00	3.70	7.00	3.70	12.5	2.00	0

RPE

Captured HR

Manual HR

PMHR: 193.00 beats/min 96.5 125.4 193

%HR max 50% 60% 100%

6 of 10

End of Section Close Exam Finish

4.5.1 Function of Treadmill Test Screen

The treadmill test is completed using the screen in Exhibit 4-28 above. The following sections will describe the buttons and functionality of this data entry screen.

4.5.1.1 Timer

The timer in the upper left of the screen will be used to time the exercise stages. When the 'Start' button is pressed, the timer begins for the Warm-up Stage. The timer counts up to 2 minutes for Warm-up, then resets to zero for the beginning of Stage 1. It then counts up to 3 minutes for Stage 1, resets to zero for the beginning of Stage 2, counts up to 3 minutes for Stage 2, then resets to zero for the

beginning of Recovery 1. The timer counts up to 1 minute for Recovery 1 and one minute for Recovery 2 and stops. If the heart rate is greater than 110 after Recovery 2, the timer will count up to 1 minute for Recovery 3 and then stop.

4.5.1.2 Start Button

The 'Start' button is used to start the timer for the exercise stages.

4.5.1.3 Restart Button

The Restart' button is used to restart the timer at zero if the test needs to be restarted. This would be used in a nonemergency situation. For example, if the test has started and the SP's shoe laces become untied, the test can be interrupted and the timer restarted. This function is only used in the Warm-up stage and during the first 15 seconds in Stage 1. The test should not be restarted for any reason after the first 15 seconds in Stage 1. See Section 3.14.

4.5.1.4 Emergency Stop Button

The Emergency Stop is used only to stop the test immediately if the condition of the SP warrants this action. This will be described in greater detail in subsequent screens.

4.5.1.5 Predetermined Protocols

The box to the right of the 'Start' button displays the predetermined protocol with the speed and grade to be used for the Warm-up, Stages 1 and 2, and for the Recovery Stages. The middle protocol is the predetermined protocol that will be used. When the Start button is pressed, the middle protocol will be highlighted in red for the current stage. The next higher and next lower protocols are also displayed in this box.

4.5.1.6 Change Protocol Button

The 'Change Protocol' button is used to increase or decrease the predetermined protocol. This button can only be used during the Warm-up stage.

4.5.1.7 Go To Recovery Button

The 'Go to Recovery' button is used to stop the exercise test at any point and go directly to Recovery. The SP will continue through the Recovery Stages but will not complete the remainder of time in the exercise stages.

4.5.1.8 Show Data Button

The 'Show Data' button is used to look at the heart rate and blood pressure from the previous stages. See Exhibit 4-33 for an example of the 'Show Data' window on the treadmill test screen.

4.5.1.9 Estimated VO₂ Max Field

The 'Estimated VO₂ max' field is used to view this variable after the treadmill test is completed. The VO₂ max is calculated and displayed after Recovery 2 has been completed.

4.5.1.10 Continuum Bar

The continuum bar has the predicted maximal heart rate (PMHR) in beats per minute on the top and the percent of the maximum heart rate (%HR) along the bottom.

- During Warm-up, the SP's heart rate should increase to approximately 60 percent of the maximum heart rate. This range is displayed on the continuum bar. If the heart rate goes higher than this, the protocol should be decreased for Stages 1 and 2.
- During Stage 1, the SP's heart rate should be about 60-80 percent of the maximum heart rate. When the ISIS system changes to Stage 1, the continuum changes to reflect

this change. If the SP's HR is above 80 percent of PMHR at any time in Stage 1, determine if the SP is OK by observing color, breathing, and gait for signs of severe fatigue and ask the SP how he or she is feeling.

- During Stage 2, the SP's heart rate should be below 85 percent of the predicted maximal heart rate (90% for SPs 12 through 18 years). The continuum changes to reflect these numbers. The ISIS system will display 85 percent or 90 percent based on the age of the SP. If the SP's HR is above these criteria at any time in Stage 2, determine if the SP is OK by observing signs and symptoms as described for Stage 1.
- During Recovery, the SP's heart rate is expected to decrease back to approximately 110 beats per minute or less. The continuum changes to reflect the 50 percent PMHR. This is used as a guideline.

4.5.2 Preparing the Treadmill and Controller

Exhibit 4-31. Preparing the treadmill and controller

The screenshot shows the 'Cardiovascular Fitness' software interface. At the top, it displays session information: 'Stand:250 Session:250140 10/20/2003 08:30 am - 12:30 pm'. Below this, participant details are shown: 'SP ID: 770676 Name: FOX, BRUCE Age: 27 years Gender: Male Date: 12/27/2003 Time: 02:37 PM'. The main area is titled 'Treadmill Test' and features a digital timer at '00:00' with 'min' and 'sec' indicators. On the left, there are three large buttons: 'START' (green), 'RESTART' (yellow), and 'EMERGENCY STOP' (red). Below these are smaller buttons for 'Change Protocol', 'Go To Recovery', and 'Show Data'. A 'Vo2 Max' field is set to '00'. The central part of the screen displays a protocol table with columns for 'WARM-UP', 'STAGE 1', 'STAGE 2', and 'RECOVERY', each with sub-columns for 'Speed' and 'Grade'. A pop-up window titled 'Cardiovascular Fitness' is overlaid on the table, containing an information icon and the text: 'Choose exercise protocol on treadmill controller. Have SP straddle the belt, then press Start Belt.' with an 'OK' button. Below the pop-up is a 'Manual HR' section with two input fields. At the bottom, a 'PMHR' field shows '193.00 beats/min'. A horizontal bar graph shows '%HR max' with markers at 50% (96.5), 60% (125.4), and 100% (193). The bottom status bar includes navigation arrows, '6 of 10', and buttons for 'End of Section', 'Close Exam', and 'Finish'.

Protocol	WARM-UP		STAGE 1		STAGE 2		RECOVERY	
	Speed	Grade	Speed	Grade	Speed	Grade	Speed	Grade
5	3.00	3.00	3.70	4.00	3.70	8.00	2.00	0
6	3.10	3.50	3.70	5.50	3.70	10.0	2.00	0
7	3.20	5.00	3.70	7.00	3.70	12.5	2.00	0

When this screen initially comes up, the ISIS system displays a visual message and gives the same auditory message:

“Choose exercise protocol on treadmill controller. Have SP straddle the belt, then press ‘Start Belt’.”

- The middle protocol is the predetermined protocol for this SP. (This would be protocol # 6 in this example.) Enter the predetermined protocol on the treadmill controller. (See Section 3.9.2 for details.)
- Press the Clear button on the treadmill controller to reset the treadmill setting.
- Press Input plus (+) or minus (–) to move through protocols 1 to 8. Select the predetermined protocol (the middle protocol on the ISIS screen)

4.5.3 Getting the SP on the Treadmill

- You just demonstrated and explained the treadmill test after the BP and HR data were captured. Now you want to get the SP on the treadmill to start the Warm-up phase. You will need to repeat the explanation step-by-step. Don't assume that the SP will know how to walk on a treadmill.
- Have the SP straddle the treadmill belt on treadmill controller.
- Press “Start Belt” and increase the speed of the treadmill to 2.0 mph.
- Repeat the explanation as outlined below.
- Get the SP to straddle the belt and hold onto the handrail with both hands.
- Tell them to ‘paw’ the belt with one foot to get a feel for the movement of the belt and then instruct them to step on the treadmill and begin to walk.
- Tell them to use an upright posture and look straight ahead. Once they have started, get them to drop one arm by their side and then the other one. Click OK.
- They should now be walking slowly on the treadmill and ready to begin the test.
- At this point they are walking very slowly and you should go to Warm-up as soon as he or she seems to be getting somewhat comfortable walking on the belt.

4.5.4 Warm-up

Exhibit 4-32. Starting the timer

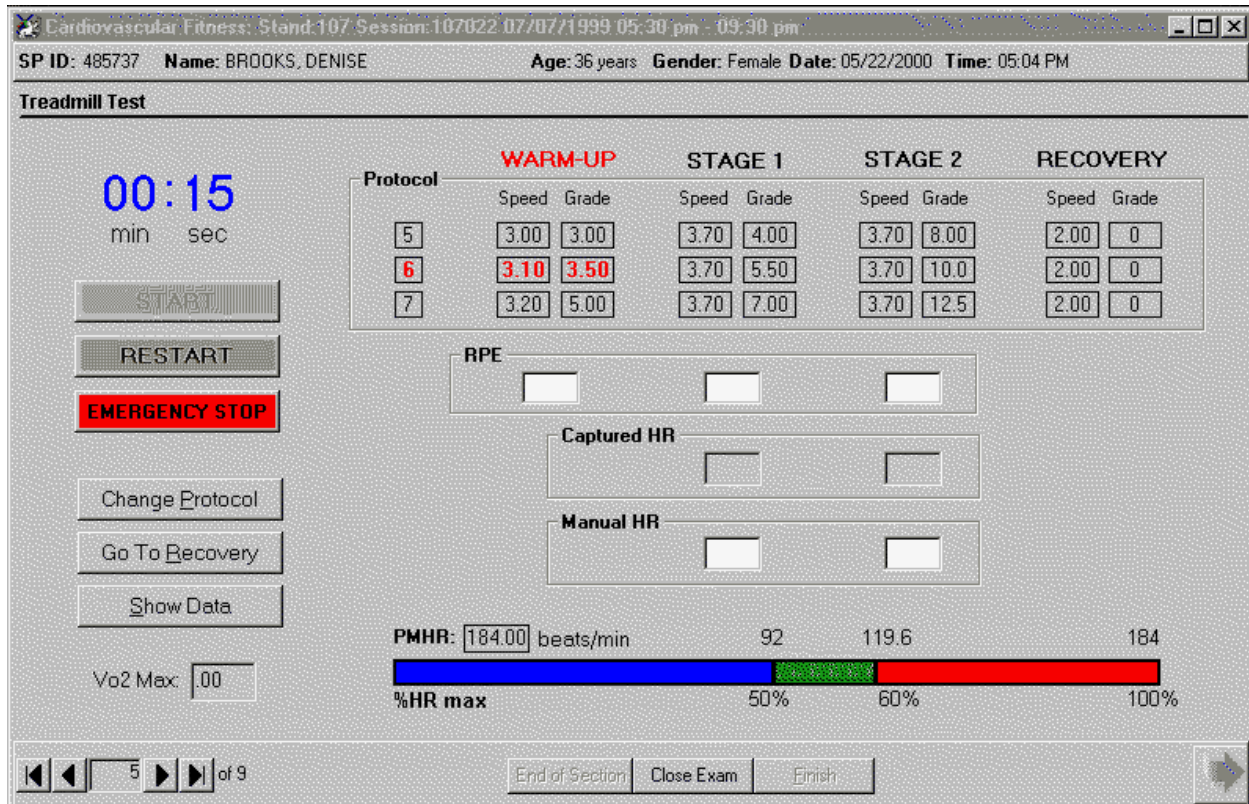
The screenshot shows a software window titled "Cardiovascular Fitness: Stand:250 Session:250140 10/20/2003 08:30 am - 12:30 pm". The user information is: SP ID: 770676, Name: FOX, BRUCE, Age: 27 years, Gender: Male, Date: 12/27/2003, Time: 02:37 PM. The test is a "Treadmill Test" with a timer showing 00:05. The protocol table is as follows:

Protocol	WARM-UP		STAGE 1		STAGE 2		RECOVERY	
	Speed	Grade	Speed	Grade	Speed	Grade	Speed	Grade
5	3.00	3.00	3.70	4.00	3.70	8.00	2.00	0
6	3.10	3.50	3.70	5.50	3.70	10.0	2.00	0
7	3.20	5.00	3.70	7.00	3.70	12.5	2.00	0

Below the table are controls for RPE, Captured HR, and Manual HR. At the bottom, a PMHR bar shows 193.00 beats/min, with a scale from 50% to 100% HR max. The bar is divided into blue (50-60%), green (60-65%), and red (65-100%) segments. The current value is 193, which is at the 100% mark. The interface also includes buttons for "START", "RESTART", "EMERGENCY STOP", "Change Protocol", "Go To Recovery", "Show Data", "Vo2 Max: .00", "End of Section", "Close Exam", and "Finish".

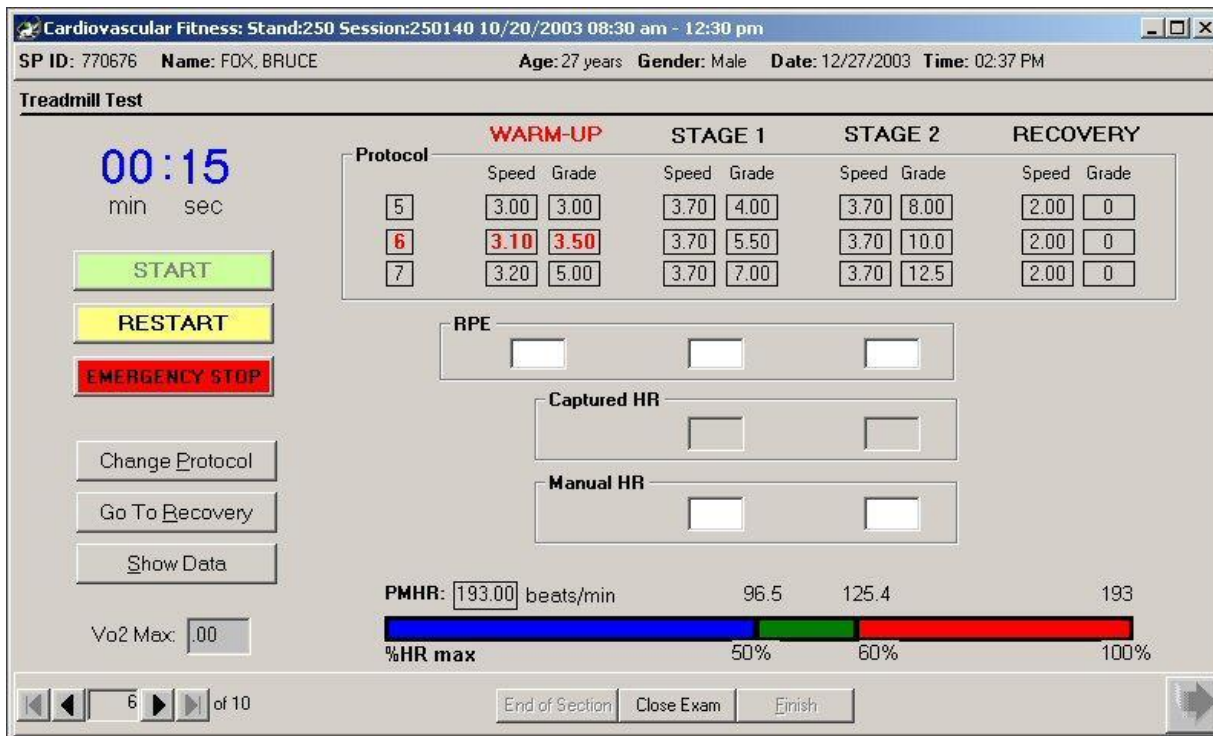
- The ISIS system will give the following auditory message:
“Simultaneously press ‘Start’ on the ISIS screen and press ‘Start Course’ on the treadmill controller.”
- Click ‘Start’ on the ISIS screen. The timer will start timing the 2-minute Warm-up Stage.
- Press ‘Start Course’ on the treadmill controller.
- The treadmill will increase to the speed and grade for the predetermined Warm-up Stage for the selected protocol.

Exhibit 4-33. Explaining the rating of perceived exertion (RPE)



- When the timer starts, the Warm-up Stage for the predetermined protocol (the middle protocol on the screen) will be highlighted in red.
- At 15 seconds into Warm-up, the ISIS system will give the auditory message:
“Explain RPE.”
- Explain the Rating of Perceived Exertion (RPE) using the standard script. See Section 3.9.7 for procedures for explaining RPE and Section 3.10 for procedures if the RPE exceeds the criteria.
- Throughout this stage, monitor the % HR scale on the ISIS screen and the SP’s current heart rate, which is displayed digitally on the BP monitor.
- The SP’s heart rate should be below 60 percent of the PMHR.

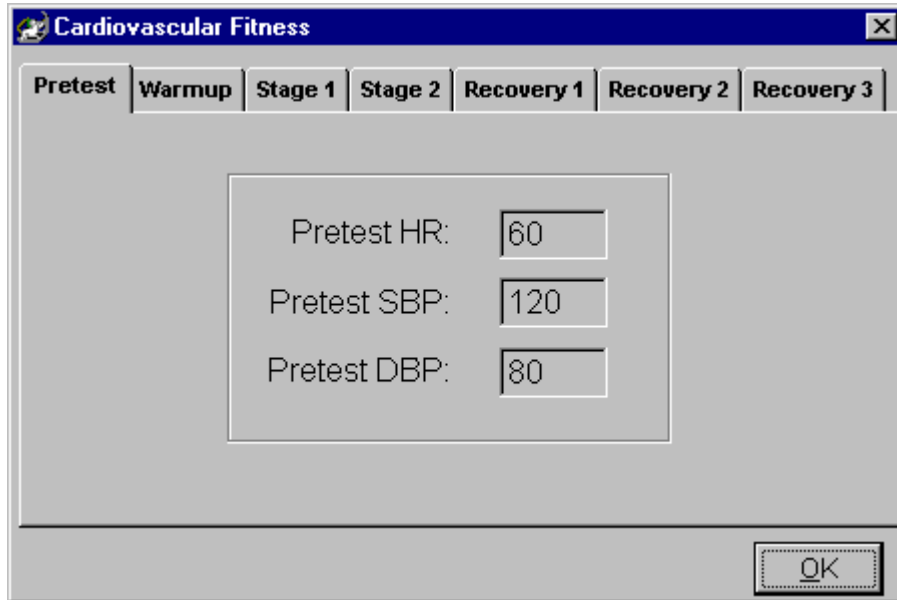
Exhibit 4-34. Getting RPE for warm-up



- At 1 minute 30 seconds into Warm-up, the ISIS system will give an auditory message:
“Get RPE Assessment.”
- Enter RPE score in the box under Warm-up.
- Note the heart rate on the monitor. The ISIS system is capturing the heart rate at this time for the Warm-up Stage. When the stage changes you can check the heart rate that was captured. At 1 minute 50 seconds into Warm-up, the ISIS system will give an auditory message:
“Press ‘Next Stage’ on treadmill controller at 1 minute 57 seconds.”
- Watch the timer and at 1:57 in Warm-up, press ‘Next Stage’ on treadmill controller. This will advance the treadmill to Stage 1 of the current protocol.

4.5.5 Show Data

Exhibit 4-35. Show data window



- The captured data can be displayed by clicking on the 'Show Data' button. The data for Pretest, Warm-up, Stage 1, Stage 2, and Recovery stages can be viewed by clicking on the tab of the stage you want to see.

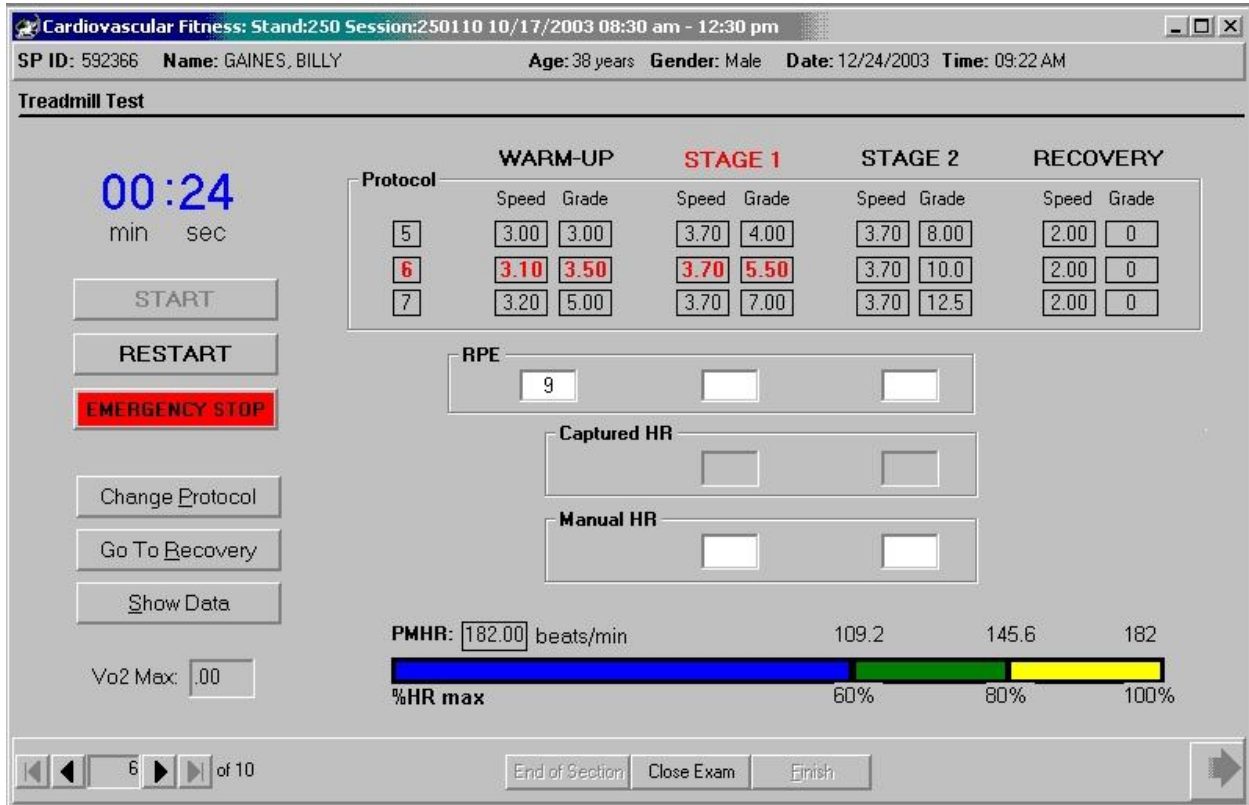
Exhibit 4-36. Show data message



- Only the data from the previous stages can be accessed. If you click on the current stage the ISIS system will display a message: 'The data you are trying to access is not available at this time.' Click OK to this message and select a tab from the previous stage. Once the current stage is completed, the data from that stage can be viewed.

4.5.6 Stage 1

Exhibit 4-37. Treadmill test stage 1 – routine test



- The ISIS system will advance to Stage 1. The timer will be reset to zero and will start timing the 3-minute Stage 1. Throughout this stage, monitor the BP monitor for the SP's heart rate. Watch the continuum bar to confirm that the SP's heart rate is within the 60 – 80 percent range.
- If the SP's heart rate goes above the 80 percent range, determine if the SP is OK by observing his or her color, breathing, and gait for signs of severe fatigue and ask how he or she is doing.
- Ask for the RPE. You do not have to record the RPE unless it is at the end of the stage. If the SP looks OK, does not ask to stop, and RPE is not greater than 17, continue with the test.
- Continue to monitor very closely for signs of exhaustion and stop the test if the SP's symptoms warrant ending the test.

Exhibit 4-38. Get rating of perceived exertion (RPE)

Cardiovascular Fitness: Stand:250 Session:250110 10/17/2003 08:30 am - 12:30 pm

SP ID: 592366 Name: GAINES, BILLY Age: 38 years Gender: Male Date: 12/24/2003 Time: 09:22 AM

Treadmill Test

02:34
min sec

START
RESTART
EMERGENCY STOP
Change Protocol
Go To Recovery
Show Data
Vo2 Max: .00

Protocol	WARM-UP		STAGE 1		STAGE 2		RECOVERY	
	Speed	Grade	Speed	Grade	Speed	Grade	Speed	Grade
5	3.00	3.00	3.70	4.00	3.70	8.00	2.00	0
6	3.10	3.50	3.70	5.50	3.70	10.0	2.00	0
7	3.20	5.00	3.70	7.00	3.70	12.5	2.00	0

RPE: 9

Captured HR

Manual HR

PMHR: 182.00 beats/min

%HR max: 109.2, 145.6, 182

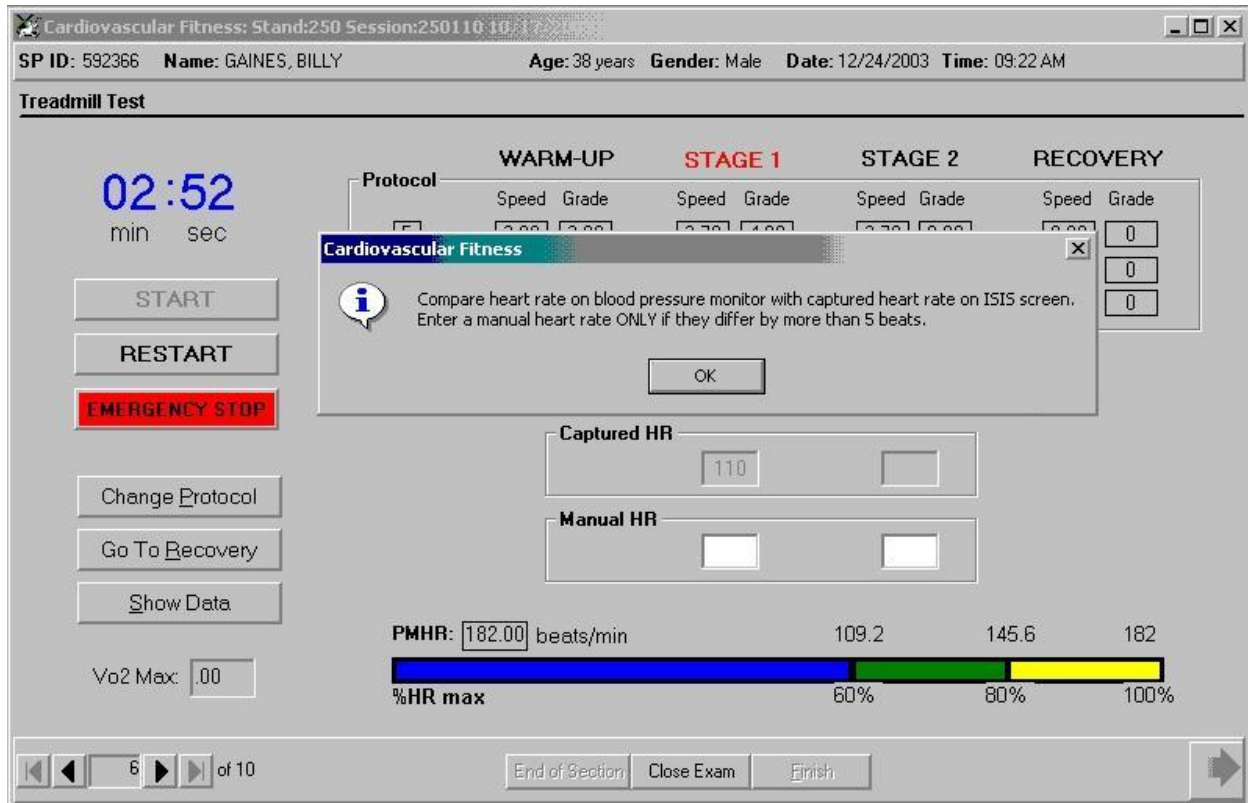
6 of 10

End of Section Close Exam Finish

- At 2 minutes 30 seconds into Stage 1 the ISIS system will give the auditory message:
“Get RPE Assessment.”
- Get the SP’s assessment of RPE and enter the number in the appropriate field below Stage 1.

4.5.6.1 Manually Entered Heart Rate

Exhibit 4-39. Compare heart rate on monitor and screen



- The BP monitor will automatically measure BP and HR. These values will be captured by the ISIS system. At approximately 2 minutes 40 seconds into Stage 1 the ISIS system will give the auditory message:
“Check heart rate on monitor.”
- The ISIS system will then display a visual message:
“Compare heart rate on blood pressure monitor with captured heart rate on ISIS screen. Enter a manual heart rate ONLY if they differ by more than 5 beats.”
- Note the heart rate on the blood pressure monitor and compare this number with the captured heart rate on the ISIS screen. If the captured heart rate on the ISIS screen does not differ by more than 5 beats from the heart rate on the BP monitor, click OK and continue the test.

Exhibit 4-40. Example 1 – manually entered heart rate - not necessary

The screenshot displays the 'Cardiovascular Fitness' software interface for a treadmill test. The window title is 'Cardiovascular Fitness: Stand:250 Session:250110 10/17/2003 08:30 am - 12:30 pm'. The patient information is: SP ID: 592366, Name: GAINES, BILLY, Age: 38 years, Gender: Male, Date: 12/24/2003, Time: 09:22 AM. The test is titled 'Treadmill Test' and shows a timer at 00:47 (00 min, 47 sec). On the left, there are buttons for 'START', 'RESTART', 'EMERGENCY STOP', 'Change Protocol', 'Go To Recovery', and 'Show Data'. The 'Vo2 Max' is set to .00. The protocol table is as follows:

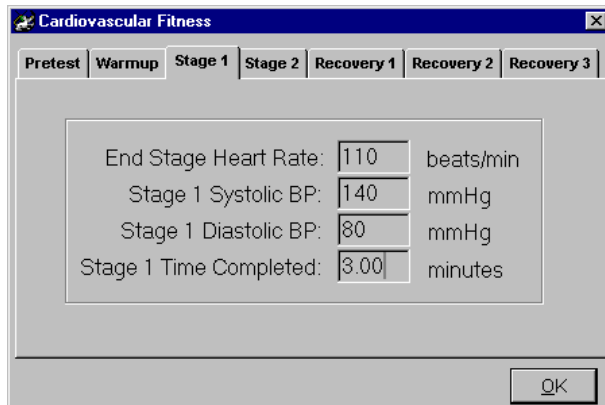
Protocol	WARM-UP		STAGE 1		STAGE 2		RECOVERY	
	Speed	Grade	Speed	Grade	Speed	Grade	Speed	Grade
5	3.00	3.00	3.70	4.00	3.70	8.00	2.00	0
6	3.10	3.50	3.70	5.50	3.70	10.0	2.00	0
7	3.20	5.00	3.70	7.00	3.70	12.5	2.00	0

Below the protocol table, there are input fields for RPE (9, 11, and an empty field), Captured HR (110), and Manual HR (two empty fields). At the bottom, the PMHR is 182.00 beats/min, and the %HR max is 85% (154.7 / 182). A progress bar shows the current heart rate relative to the maximum. The interface also includes navigation buttons at the bottom: 'End of Section', 'Close Exam', 'Finish', and a right arrow.

If the heart rate on the blood pressure monitor is within 5 beats of the captured heart rate, it should not be entered manually. The ISIS system will accept the captured heart rate.

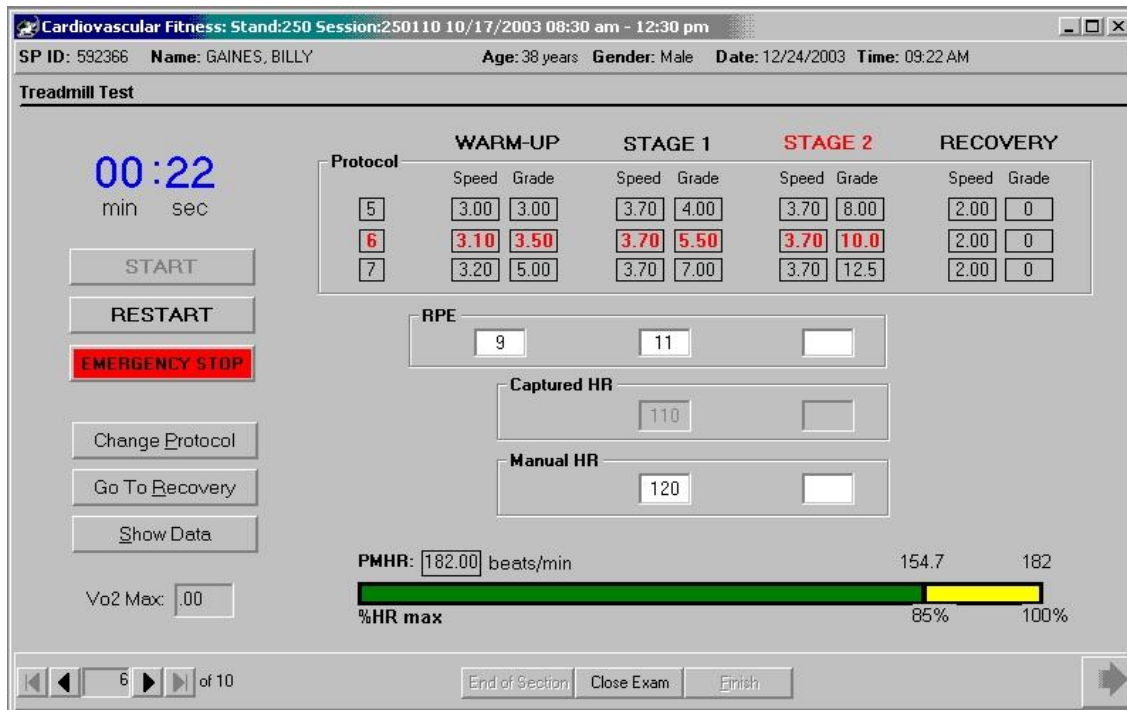
- Example 1: In the example above, the ISIS system captured the heart rate on the ISIS screen as 110.

Exhibit 4-41. Show data screen for Example 1



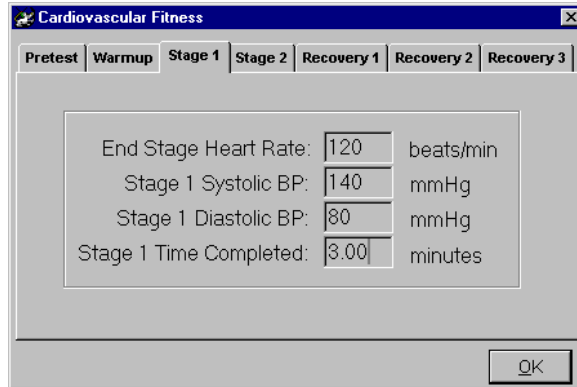
- If the heart rate on the BP monitor was 112 and the captured heart rate on the ISIS screen is 110 (as in the above example), it is not necessary to enter 112 in the manual heart rate field. The ISIS system will store 110 to the "show data" field and use it as the heart rate for calculation of VO_{2max} .

Exhibit 4-42. Example 2 – manually entered heart rate - necessary



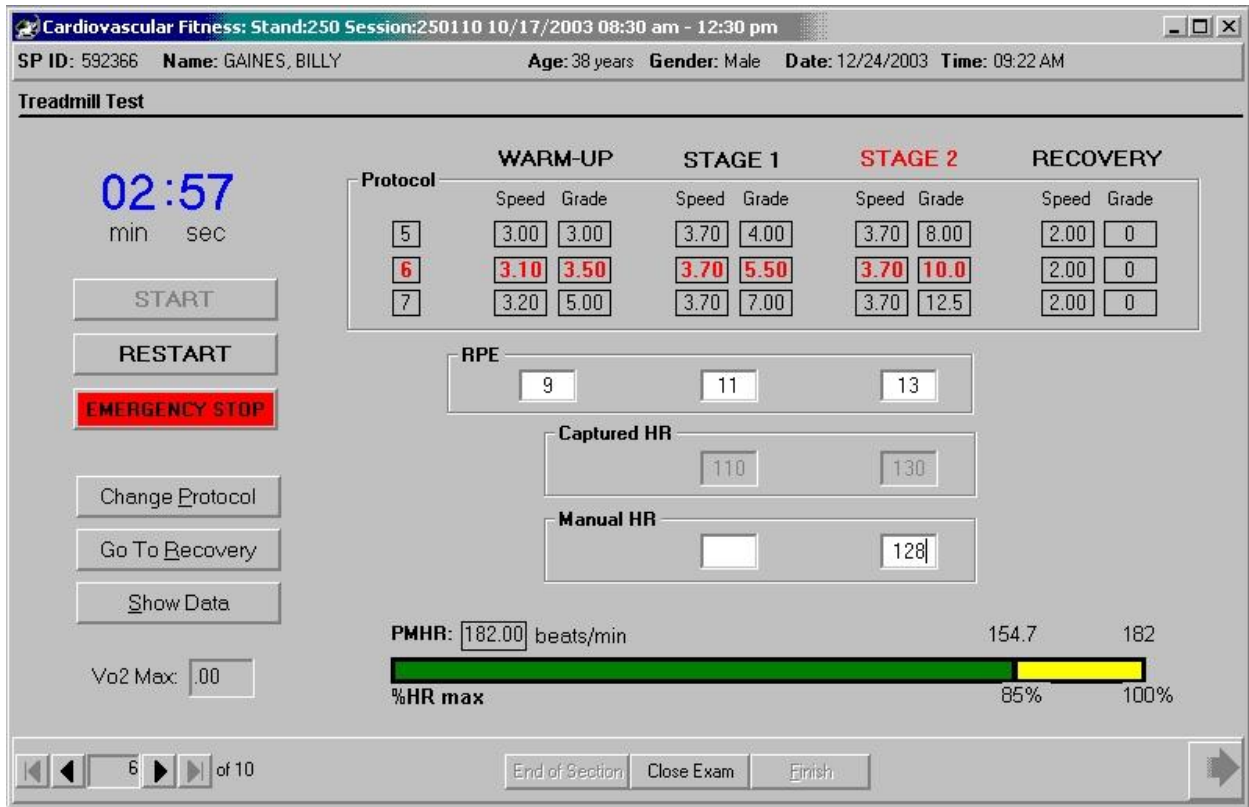
- Example 2: In the above example, the ISIS system captured the heart rate as 110. The technician noticed that the heart rate was actually 120 at the time of data capture. This is not within 5 beats of the captured value, so the technician manually entered 120 in the heart rate field.

Exhibit 4-43. Show data window for Example 2.



- The ISIS system will save both values but will store 120 to the "show data" field and use it as the heart rate for calculation of VO_2 max. This is an example of a correct data entry for manual heart rate.

Exhibit 4-44. Example 3 - manually entered heart rate - incorrect data entry



- Example 3: In the above example for Stage 2, the ISIS system captured the heart rate as 130. The technician noticed that the heart rate was actually 128 at the time of data capture. This is within 5 beats of the captured value, but the technician manually entered 128 in the heart rate field. This is an example of an incorrect data entry for this field. The heart rate did not have to be entered manually because the captured heart rate was within 5 beats of the heart rate noted on the blood pressure monitor.

Exhibit 4-45. Show data window for Example 3

The screenshot shows a software window titled "Cardiovascular Fitness" with a tabbed interface. The "Stage 2" tab is selected. The window displays the following data:

End Stage Heart Rate:	130	beats/min
Stage 2 Systolic BP:	160	mmHg
Stage 2 Diastolic BP:	80	mmHg
Stage 2 Time Completed:	3:00	minutes

An "OK" button is located at the bottom right of the window.

- In the example above, the manually entered HR (128 for Stage 2) is not necessary and should not have been entered. In this situation, the ISIS system will save both values but will store 130 to the 'show data' field, and will use this for calculation of the VO_2 max.

Exhibit 4-46. Manual entry fields disabled

The screenshot shows a software window titled "Cardiovascular Fitness: Stand:250 Session:250110 10/17/2003 08:30 am - 12:30 pm". The patient information is: SP ID: 592366, Name: GAINES, BILLY, Age: 38 years, Gender: Male, Date: 12/24/2003, Time: 09:22 AM. The test is a "Treadmill Test" with a timer at 00:14. The protocol table is as follows:

Protocol	WARM-UP		STAGE 1		STAGE 2		RECOVERY	
	Speed	Grade	Speed	Grade	Speed	Grade	Speed	Grade
5	3.00	3.00	3.70	4.00	3.70	8.00	2.00	0
6	3.10	3.50	3.70	5.50	3.70	10.0	2.00	0
7	3.20	5.00	3.70	7.00	3.70	12.5	2.00	0

Below the table, RPE values are 9, 11, and 13. Captured HR values are 110 and 130. Manual HR values are empty and 128. PMHR is 182.00 beats/min, and %HR max is 50%. The interface includes buttons for START, RESTART, EMERGENCY STOP, Change Protocol, Go To Recovery, Show Data, and navigation controls at the bottom.

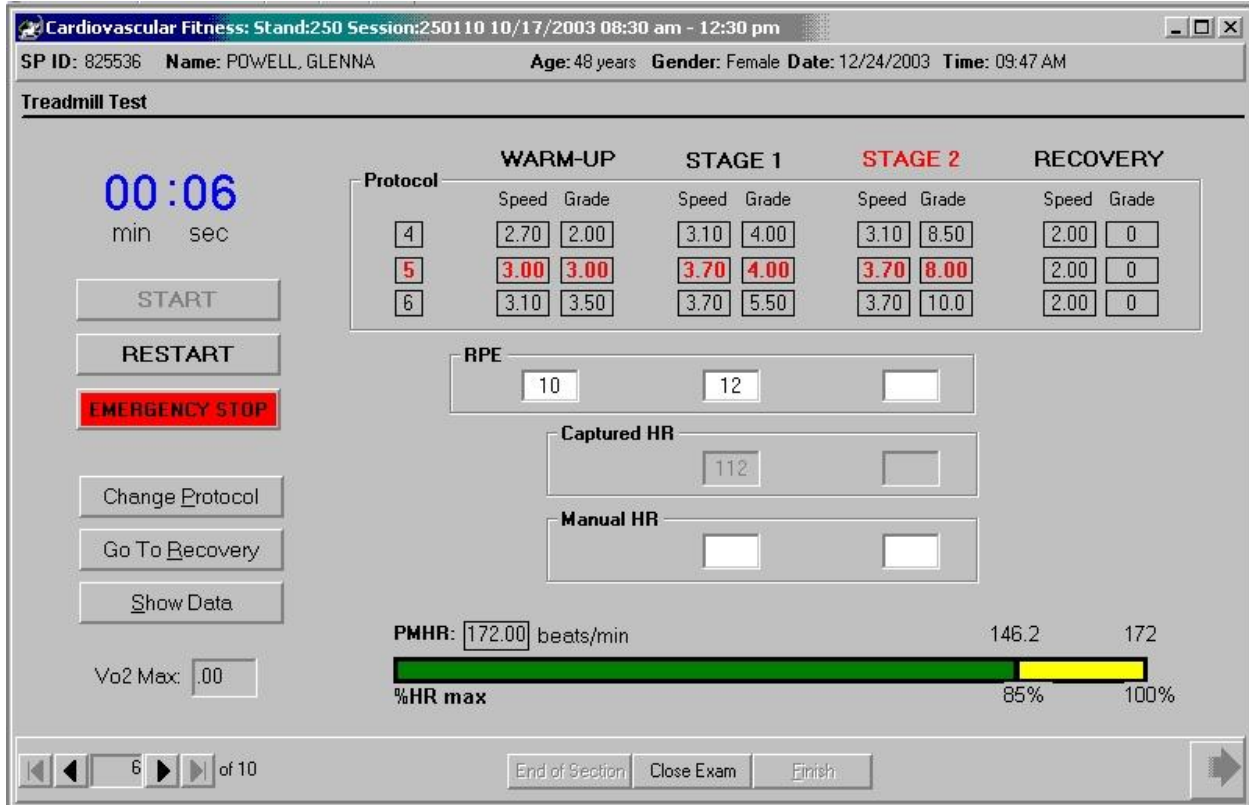
- The fields for manual entry of heart rate are disabled after Recovery 2 is completed. At this point, the VO₂ max is calculated and the ISIS system will not allow a change to be made to the heart rate.

End of Stage 1:

- After 3 minutes in Stage 1 the ISIS system will advance to Stage 2. The treadmill controller will automatically increase the speed and grade of the treadmill. The timer will be reset to zero and will start timing the 3-minute Stage 2.

4.5.7 Stage 2

Exhibit 4-47. Treadmill test stage 2 – (19 through 49 years)



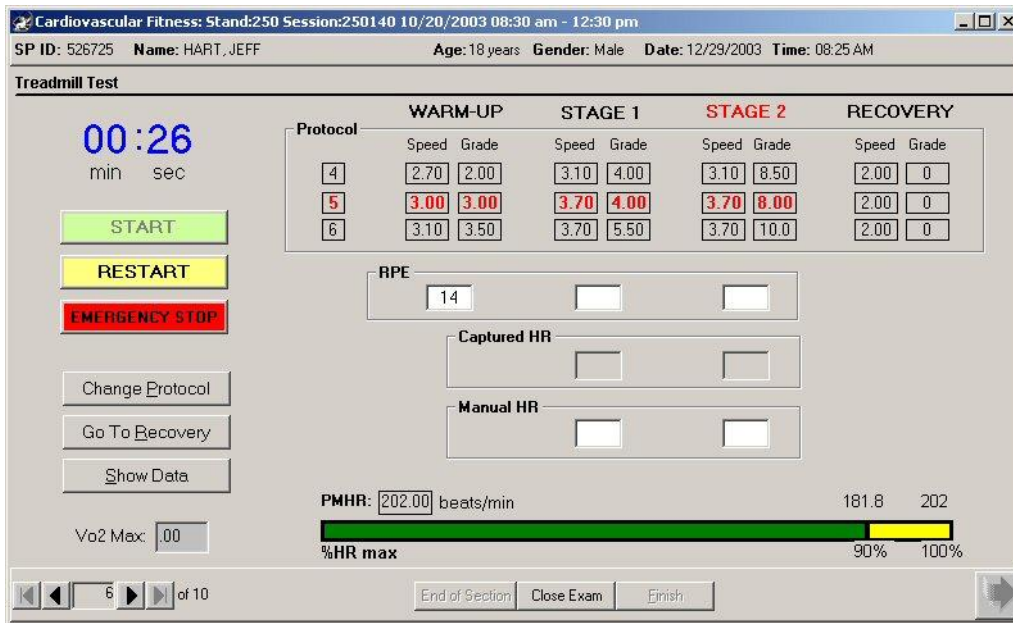
- After 3 minutes in Stage 1 the ISIS system will advance to Stage 2. The treadmill controller will automatically increase the speed and grade of the treadmill. The timer will be reset to zero and will start timing the 3-minute Stage 2.

19- through 48-year-olds:

- Throughout this stage, monitor the BP monitor for the SP's heart rate. Watch the continuum bar to confirm that the SP's heart rate is below 85 percent of PMHR.
- If the SP's heart rate is above the 85 percent range, determine if the SP is OK by observing his or her color, breathing, and gait for signs of severe fatigue and ask how he or she is doing.
- Ask for the RPE. You do not have to record the RPE unless it is at the end of the stage. If the SP looks OK, does not ask to stop, and RPE is not greater than 17, continue with the test.

- Continue to monitor very closely for signs of exhaustion and stop the test if the SPs symptoms warrant ending the test.
- At 2 minutes 30 seconds into Stage 2 the ISIS system will give the auditory message:
“Get RPE Assessment.”
- Get the SP’s assessment of RPE and enter the number in the appropriate field below Stage 2.
- The BP monitor will automatically measure BP and HR. These values will be captured by the ISIS system. At approximately 2 minutes 40 seconds into Stage 2 the ISIS system will give the auditory message:
“Check heart rate on monitor.”
- The ISIS system will then display a visual message:
“Compare heart rate on blood pressure monitor with captured heart rate on ISIS screen. Enter a manual heart rate ONLY if they differ by more than 5 beats.”
- Note the heart rate on the blood pressure monitor and compare this number with the captured heart rate on the ISIS screen. Follow the same rules in Section 4.4.6.1 for manual entry of heart rate.

Exhibit 4-48. Treadmill test stage 2 – (12 through 18 years)



12- through 18-Year-Olds:

- Throughout this stage, monitor the BP monitor for the SP's heart rate. Watch the continuum bar to confirm that the SP's heart rate is below 90 percent of PMHR.
- If the SP's heart rate is above the 90 percent range, determine if the SP is OK by observing his or her color, breathing and gait for signs of severe fatigue and ask how he or she is doing.
- Ask for the RPE. You do not have to record the RPE unless it is at the end of the stage. If the SP looks OK, does not ask to stop, and RPE is not greater than 17, continue with the test.
- Continue to monitor very closely for signs of exhaustion and stop the test if the SP's symptoms warrant ending the test.
- At 2 minutes 30 seconds into Stage 2 the ISIS system will give the auditory message:
"Get RPE Assessment."
- Get the SP's assessment of RPE and enter the number in the appropriate field below Stage 2.
- The BP monitor will automatically measure BP and HR. These values will be captured by the ISIS system. At approximately 2 minutes 40 seconds into Stage 2 the ISIS system will give the auditory message:
"Check heart rate on monitor."

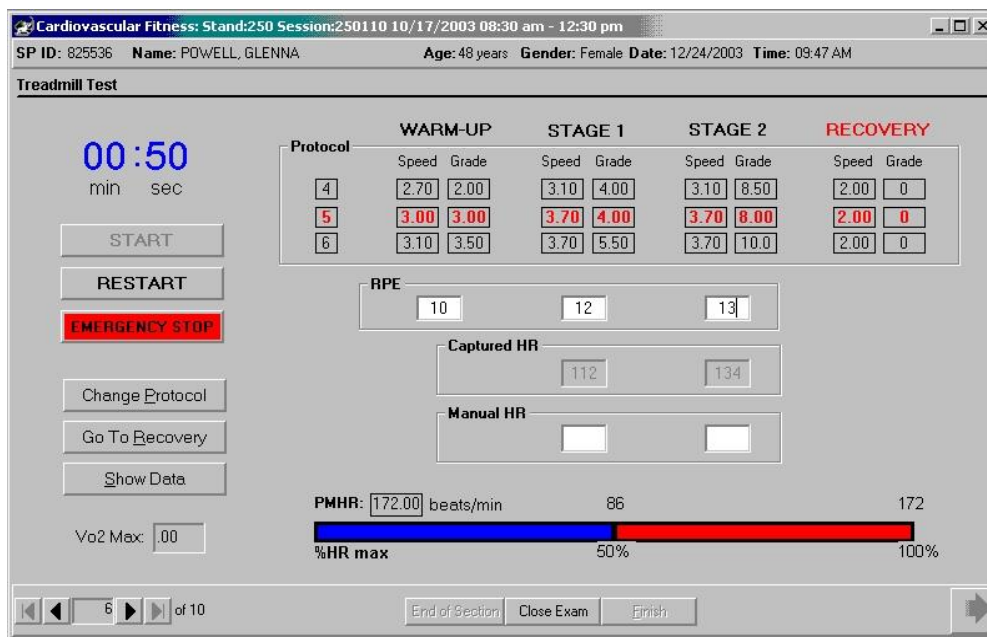
- The ISIS system will then display this visual message:

“Compare heart rate on blood pressure monitor with captured heart rate on ISIS screen. Enter a manual heart rate ONLY if they differ by more than 5 beats.”

- Note the heart rate on the blood pressure monitor and compare this number with the captured heart rate on the ISIS screen. Follow the same rules in Section 4.4.6.1 for manual entry of heart rate.

4.5.8 Recovery Stages

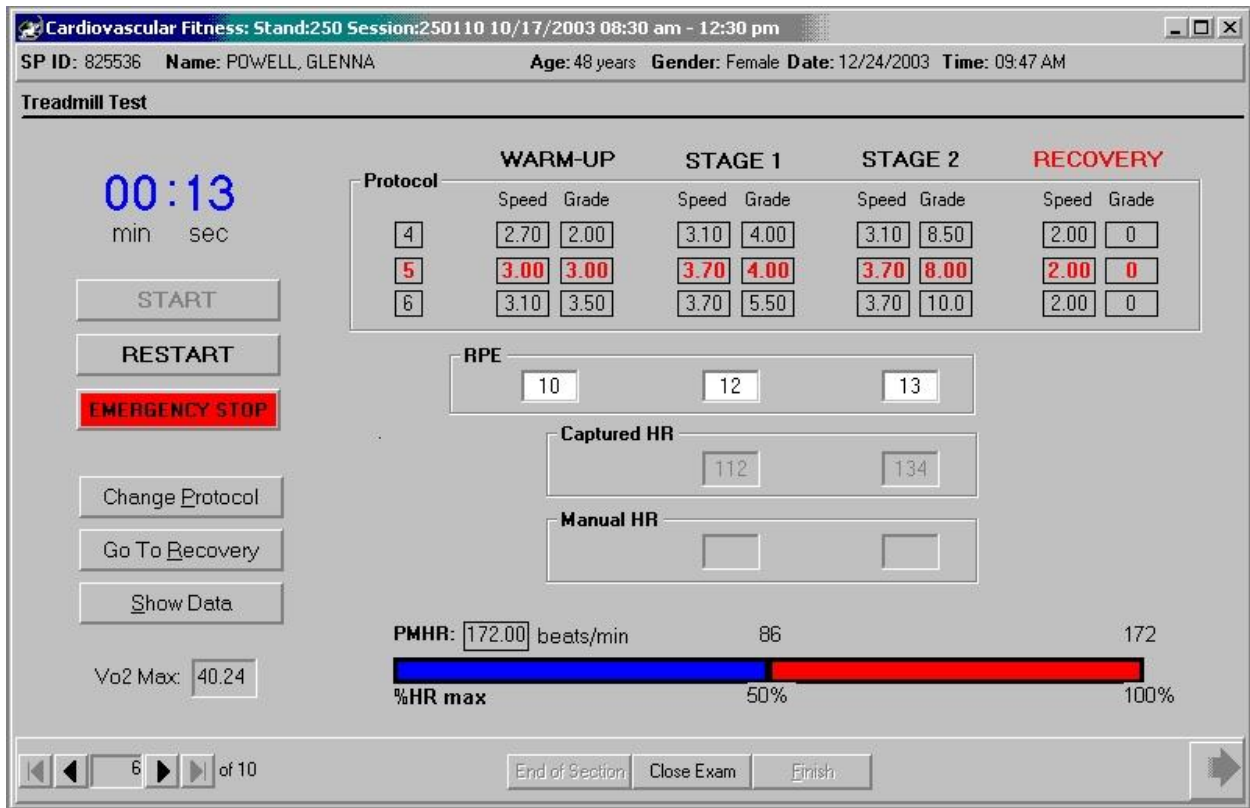
Exhibit 4-49. Treadmill test, recovery – routine test



- The ISIS system will advance to Recovery 1. The timer will be reset to zero and will start timing the 1-minute Recovery Stage. The BP monitor will automatically measure BP and HR. These values will be captured by the ISIS system.
- After 1 minute in Recovery 1, the ISIS system will advance to Recovery 2 for an additional minute. If the SP’s HR is above 110 at the end of Recovery 2, the ISIS system will give an auditory message:
“Proceed with Recovery 3.”
- Recovery will continue for 1 minute, then stop as described below. If the SP’s heart rate is 110 or below, the ISIS system will give an auditory message:
“Press ‘Cool Down’ on treadmill controller.”
- Tell SP to grasp the front of the handrail and warn him/her that the treadmill is about to stop. The ISIS system will give the following auditory message:
“Press ‘Stop’ on treadmill controller. Congratulations, you have completed the test.”
- The timer will stop and return to zero.

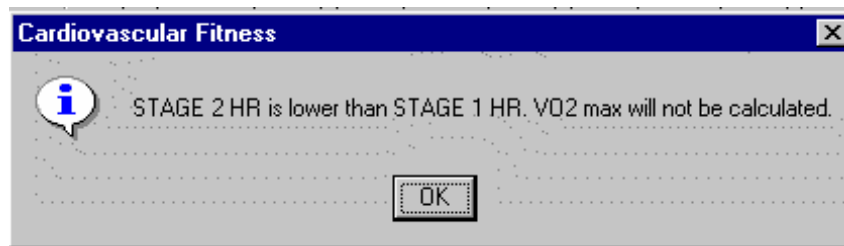
4.5.9 Checking Estimated VO₂ Max

Exhibit 4-50. Checking estimated VO₂ max



- The estimated VO₂ max is calculated after Recovery 2 and displayed in the VO₂Max field.
- The SP will be given the results of this exam in the Report of Findings. This estimate of VO₂ max will be used to determine how the SP's fitness level compares to other people of similar age and gender.

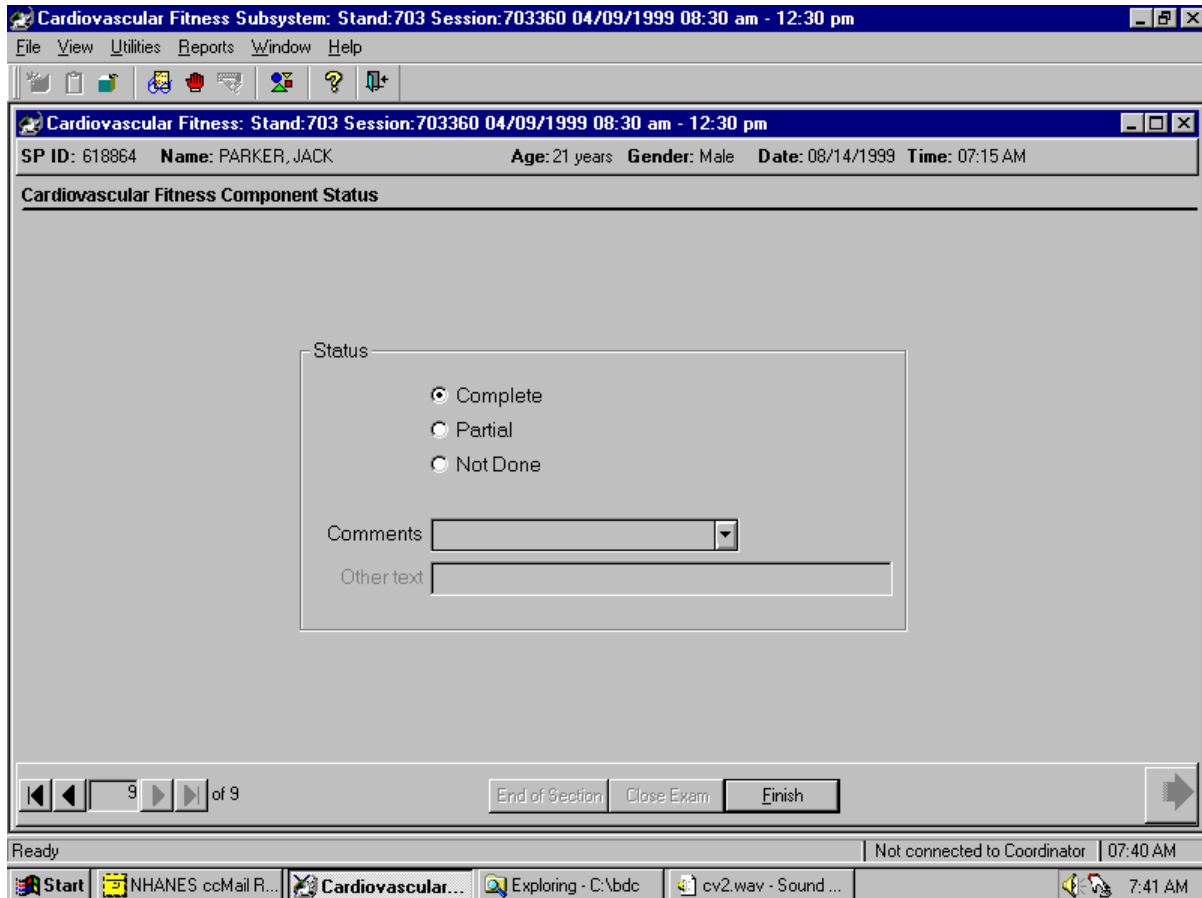
Exhibit 4-51. VO₂ max not calculated



- If the heart rate at Stage 2 is lower than the heart rate at Stage 1, the ISIS system will display the above message and the VO₂ will not be calculated.

4.5.10 Component Status for Routine Test

Exhibit 4-52. Component status - complete

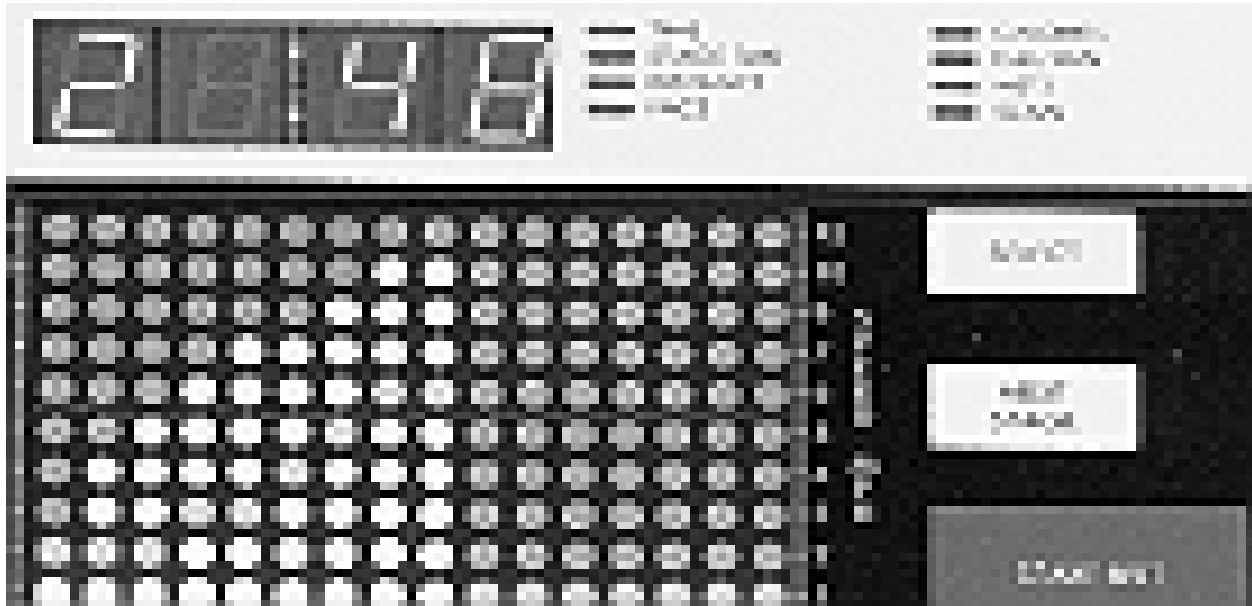


- At the end of the test, the ISIS system will advance to the Component Status screen.
- The Component Status will be set to 'Complete.'
- Press the 'Finish' button to close the exam.

4.6 Changing the Exercise Protocol

4.6.1 Changing the Treadmill Controller

Exhibit 4-53. Treadmill controller



WmUp
Stg1 Cur
Stg2 Cur
Rec Cur
Stg1 Low
Stg2 Low
Rec Low
Stg1 High
Stg2 High
Rec High
Stg1 Low
Stg2 Low
Rec Low
Stg1 High
Stg2 High
Rec High

- There are 16 horizontal lights on the treadmill controller display (See Exhibit 4-52) to represent the predetermined protocols, including the currently selected protocols and the ones in the next lower and next higher levels.
- ‘WmUp’ is the Warmup Stage of the current protocol. ‘Stg 1 Cur’ is Stage 1 of the current protocol, ‘Stg 2 Cur’ is Stage 2 of the current protocol and ‘Rec Cur’ is the Recovery Stage of the current protocol. If the protocol does not have to be changed during the test, the controller will advance through these four stages only.
- ‘Stg 1 Low’ is Stage 1 for the next lower protocol, ‘Stg 2 Low’ is Stage 2 for the next lower protocol, and ‘Rec Low’ is the Recovery Stage for the next lower protocol. If the protocol has to be decreased, when the stage changes from Warmup to Stage 1, Press ‘Next Stage’ **slowly** until you get to ‘Stg 1 Low.’
- ‘Stg 1 High is Stage 1 for the next higher protocol, ‘Stg 2 High’ is Stage 2 for the next higher protocol, and ‘Rec High’ is the Recovery Stage for the next higher protocol. If the protocol has to be increased, when the stage changes from Warmup to Stage 1, Press ‘Next Stage’ **slowly** until you get to ‘Stg 1 High.’

4.6.2 Decreasing the Exercise Protocol

Exhibit 4-54. Decreasing the exercise protocol

The screenshot displays the 'Cardiovascular Fitness' software interface for a treadmill test. The window title is 'Cardiovascular Fitness: Stand:250 Session:250110 10:10:17'. The patient information is: SP ID: 680786, Name: PETERS, COLIN, Age: 30 years, Gender: Male, Date: 12/24/2003, Time: 10:00 AM. The test is titled 'Treadmill Test' and shows a timer at 01:29 (min sec). On the left, there are buttons for 'START', 'RESTART', 'EMERGENCY STOP', 'Change Protocol', 'Go To Recovery', and 'Show Data'. The 'Change Protocol' button is highlighted. The protocol table is as follows:

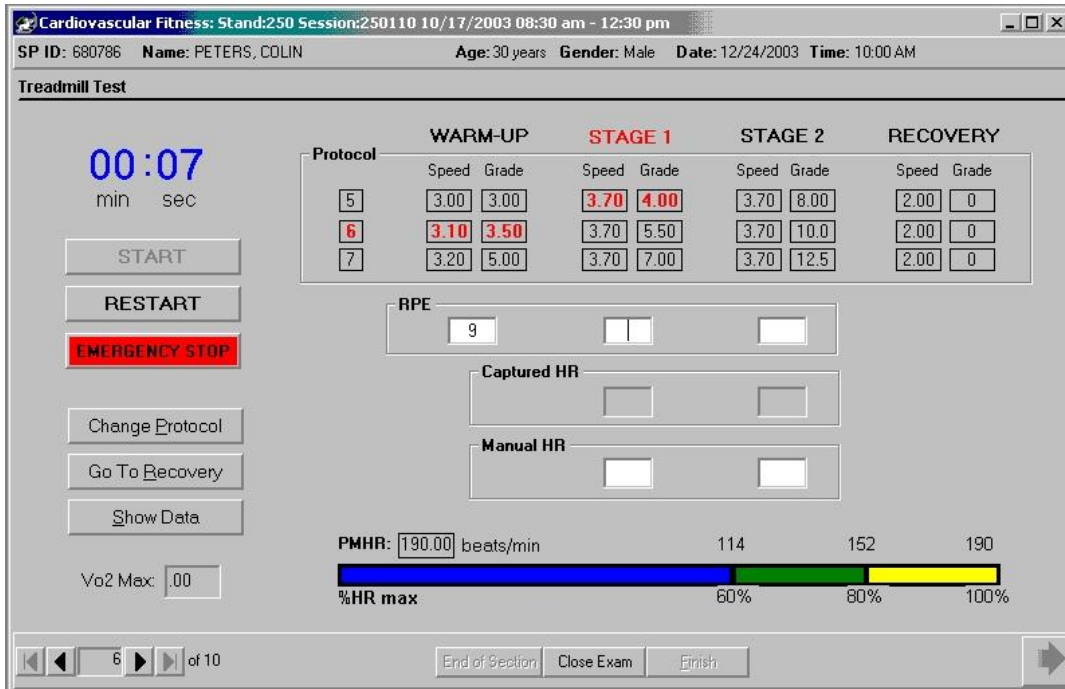
Protocol	WARM-UP		STAGE 1		STAGE 2		RECOVERY	
	Speed	Grade	Speed	Grade	Speed	Grade	Speed	Grade
5	3.00	3.00	3.70	4.00	3.70	8.00	2.00	0
6	3.10	3.50	3.70	5.50	3.70	10.0	2.00	0
7	3.20	5.00	3.70	7.00	3.70	12.5	2.00	0

The 'Change Protocol' dialog box is open, showing 'Change Protocol: 7' and 'Apply' and 'Cancel' buttons. Below the dialog, the RPE is 9, and there are fields for 'Captured HR' and 'Manual HR'. A heart rate bar shows PMHR: 190.00 beats/min, with a scale from 50% (95) to 100% (190). The current heart rate is 114, which is 60% of PMHR. The bar is color-coded: blue for 50-60%, green for 60-70%, and red for 70-100%. At the bottom, there are navigation buttons: 'End of Section', 'Close Exam', 'Finish', and a right arrow.

- If the heart rate is greater than 60 percent of PMHR during Warm-up, the protocol should be decreased for the remainder of the exam. Watch the heart during Warm-up. You need to make a decision to change the protocol by 1 minute 30 seconds into Warm-up to allow time to initiate the changes.
- Click the 'Change Protocol' button. A box with change protocol options will be displayed. Click the down arrow to decrease the protocol. Click 'Apply.' The ISIS system will give an auditory message:

"When this stage changes, change treadmill controller to the next lower protocol."

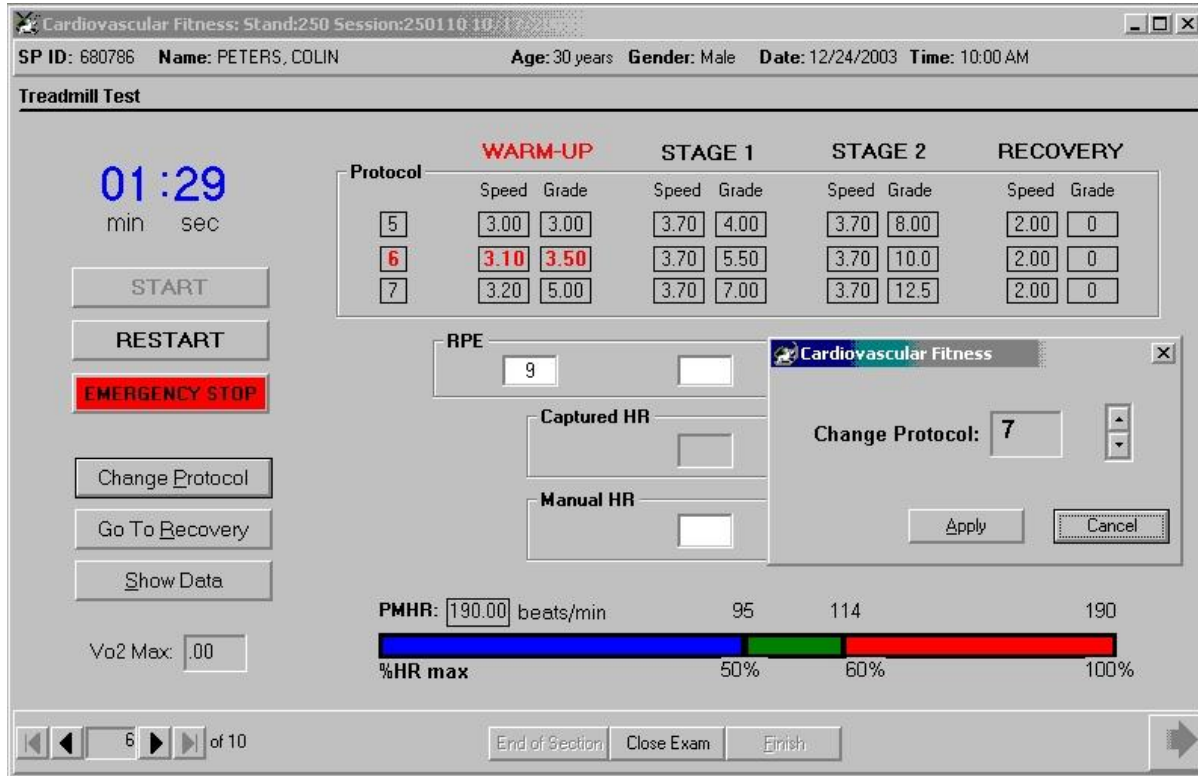
Exhibit 4-55. Decreased protocol



- Find Stage 1 of the next lower protocol. When the stage changes, press ‘Next Stage’ on the treadmill controller **slowly** until you get to ‘Stg 1 Low’ for the next lower protocol. It is important to wait until the stage changes before changing the controller.
- If you press too quickly and go past the desired protocol, keep pressing ‘Next Stage’ to advance to the second set of protocols. The next lower and next higher protocols are programmed twice in sequence. Look for Stage 1 of the next lower protocol and press ‘Next Stage’ **slowly** until you get to the desired protocol.
- When the protocol is changed, the ISIS system will advance to Stage 1 and will automatically select the next lower protocol.
- The protocol will be highlighted in red below Stage 1. The same protocol will be used for Stage 2.
- In contrast, the treadmill controller does not move to the next lower protocol automatically, even though ISIS was changed. It is necessary to manually change the setting on the treadmill controller to advance to Stage 1 on the next lower protocol.
- When the timer in the ISIS screen is reset to zero and starts timing the 3-minute Stage 1, press ‘Next Stage’ on the treadmill controller **slowly** until you get to ‘Stg 1 Low’ for the next lower protocol. It is important to wait until the stage changes before changing the controller.
- If you press too quickly and go past the desired protocol, keep pressing ‘Next Stage’ to advance to the second set of protocols. The next lower and next higher protocols are programmed twice in sequence. Look for Stage 1 of the next lower protocol and press ‘Next Stage’ **slowly** until you get to the desired protocol.
- When the protocol changes to Stage 2, the treadmill controller will now go automatically to Stage 2 of the current protocol (the lower protocol).

4.6.3 Increasing the Exercise Protocol

Exhibit 4-56. Increasing the exercise protocol



- The method for increasing the protocol is similar to decreasing the protocol. If the heart rate is less than 50 percent during Warm-up, you should increase the protocol for the remainder of the exam.
- Click 'Change Protocol' button. Click the up arrow to increase the protocol. Click Apply.
- The ISIS system will give an auditory message:
"At the beginning of the next stage, change treadmill controller to the next higher protocol."
- When the Warm-up is finished, the ISIS system will advance to Stage 1 and will automatically select the next higher protocol. This protocol will be highlighted in red below Stage 1. The same protocol will be used for Stage 2.
- In contrast, the treadmill controller does not move to the next higher protocol automatically even though ISIS was changed. Press 'Next Stage' on the treadmill controller to advance to Stage 1 on the next higher protocol.
- When the protocol changes to Stage 2, the treadmill controller will now go automatically to Stage 2 of the current protocol (the higher protocol).

Exhibit 4-57. Changing the protocol in stage 1 or 2 - message

The screenshot shows the Cardiovascular Fitness software interface. At the top, it displays 'Cardiovascular Fitness: Stand:250 Session:250110 ID: 1'. Below this, user information is shown: 'SP ID: 680786 Name: PETERS, COLIN Age: 30 years Gender: Male Date: 12/24/2003 Time: 10:00 AM'. The main section is titled 'Treadmill Test' and features a large digital timer showing '01:08' (01 min, 08 sec). To the left of the timer are buttons for 'START', 'RESTART', 'EMERGENCY STOP', 'Change Protocol', 'Go To Recovery', and 'Show Data'. The 'EMERGENCY STOP' button is highlighted in red. In the center, there is a table of exercise protocols:

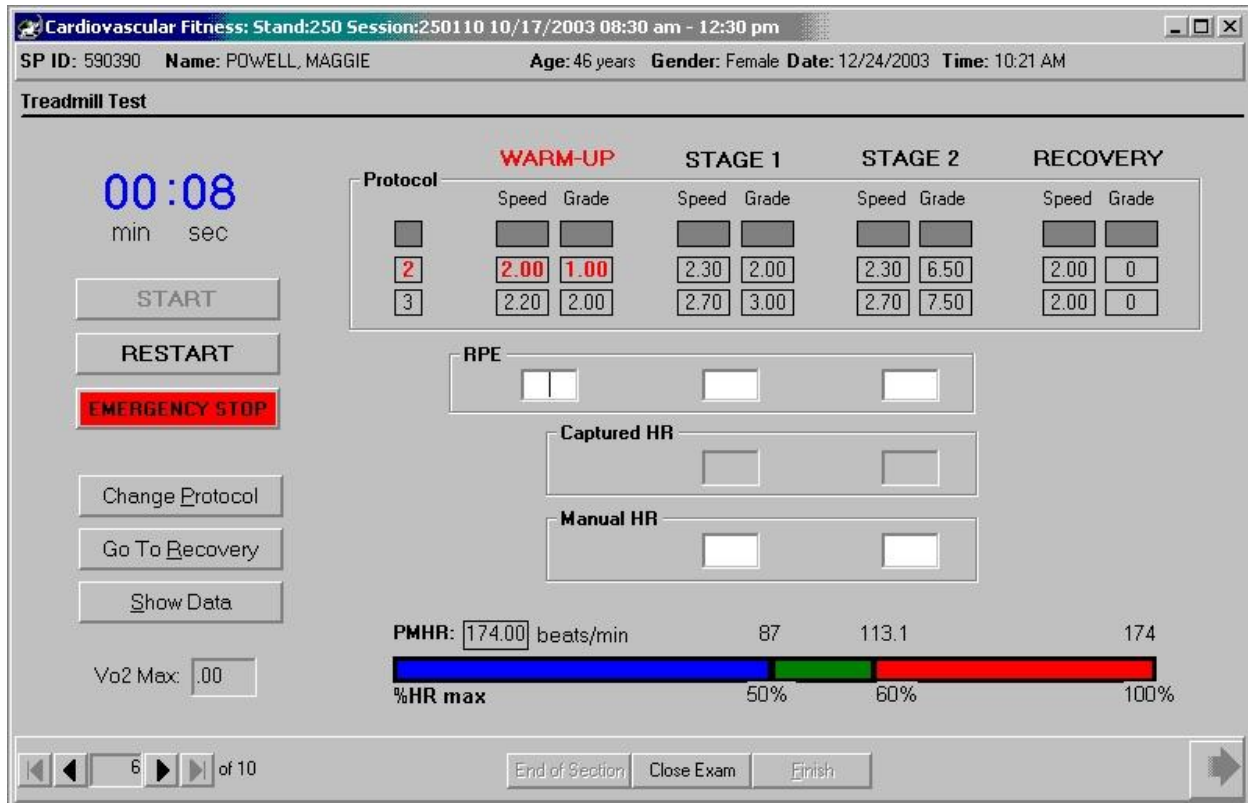
Protocol	WARM-UP		STAGE 1		STAGE 2		RECOVERY	
	Speed	Grade	Speed	Grade	Speed	Grade	Speed	Grade
5	3.00	3.00	3.70	4.00	3.70	8.00	2.00	0
6	3.10	3.50	3.70	5.50	3.70	10.0	2.00	0
7	3.20	5.00	3.70	7.00	3.70	12.5	2.00	0

Below the table, a message dialog box is open with the title 'Cardiovascular Fitness' and the message: 'The protocol cannot be changed after warmup.' with an 'OK' button. At the bottom of the interface, there is a 'PMHR' section showing '190.00 beats/min' and a '%HR max' progress bar with markers at 60%, 80%, and 100%. The progress bar is currently at approximately 60%. Navigation buttons at the bottom include 'End of Section', 'Close Exam', and 'Finish'.

- The exercise protocol may only be changed during Warm-up.
- If you click on the 'Change Protocol' button during Stage 1 or Stage 2, the ISIS system will display a message:
 - *'The protocol cannot be changed after warm-up.'*
- Click OK.
- If there is an indication to change the protocol during Stage 1 or Stage 2, use 'Go to Recovery' or 'Emergency Stop.' (See Sections 4-6 to 4-8 for detailed procedures).

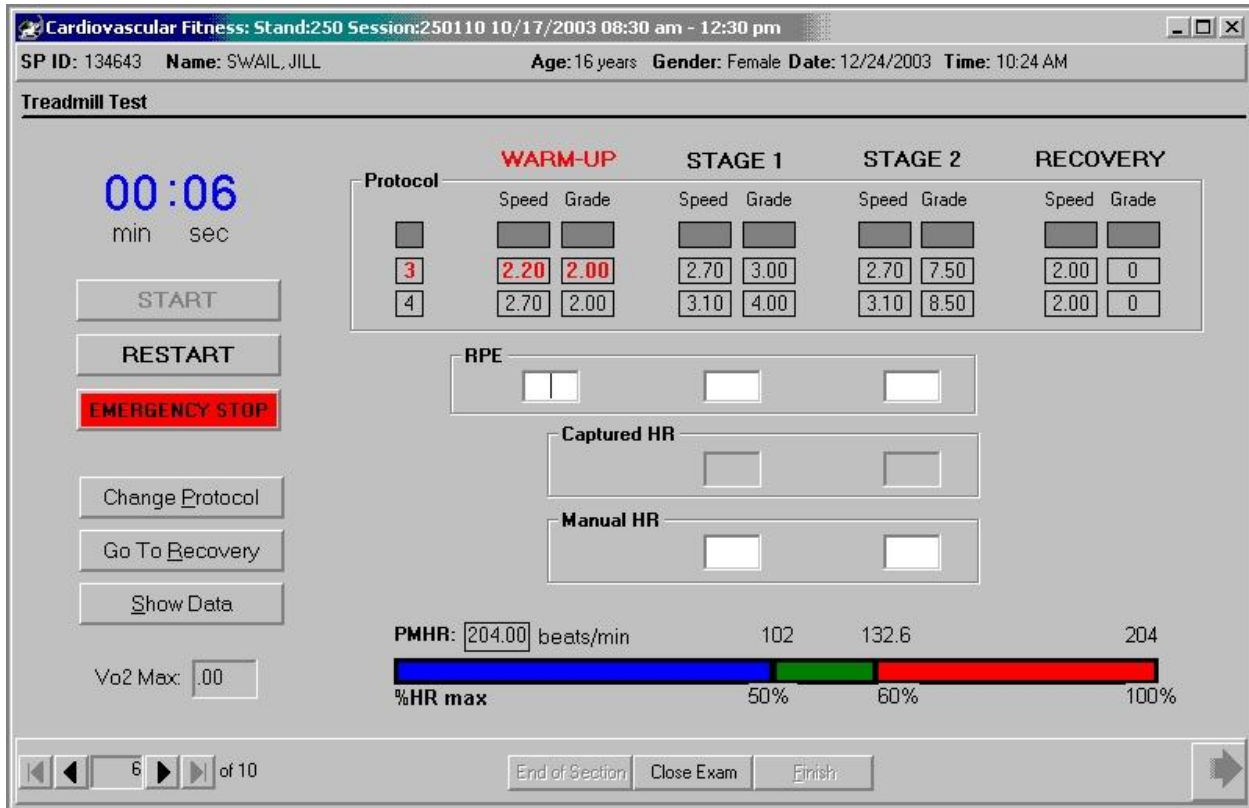
4.6.4 Lowest and Highest Protocol

Exhibit 4-58. Lowest protocol for 19 through 49 years



- See Chapter 3, Section 3.7 for details on assignment of exercise protocol. Protocols 1 and 8 will not be used. If Protocol 1 is the assigned protocol, the SP will be assigned to the next higher protocol. Protocol 1 is grayed out on the ISIS screen.
- If the predetermined protocol is 2 (the lowest protocol in the program for this age group) and the heart rate is greater than 60 percent of PMHR during Warm-up, the protocol will remain unchanged due to the unavailability of the next lower protocol.

Exhibit 4-59. Lowest protocol for 12 through 18 year olds



- See Chapter 3, Section 3.7 for details on assignment of exercise protocol. Protocols 1, 2 and 8 will not be used. If Protocol 1 or 2 is the assigned protocol, the SP will be re-assigned to Protocol 3. Protocols 1 and 2 will be grayed out on the ISIS screen.
- If the predetermined protocol is 3 (the lowest protocol in the program for this age group) and the heart rate is greater than 60 percent of PMHR during Warm-up, the protocol will remain unchanged due to the unavailability of the next lower protocol.

Exhibit 4-60. Highest protocol for all age groups (12 through 49 years)

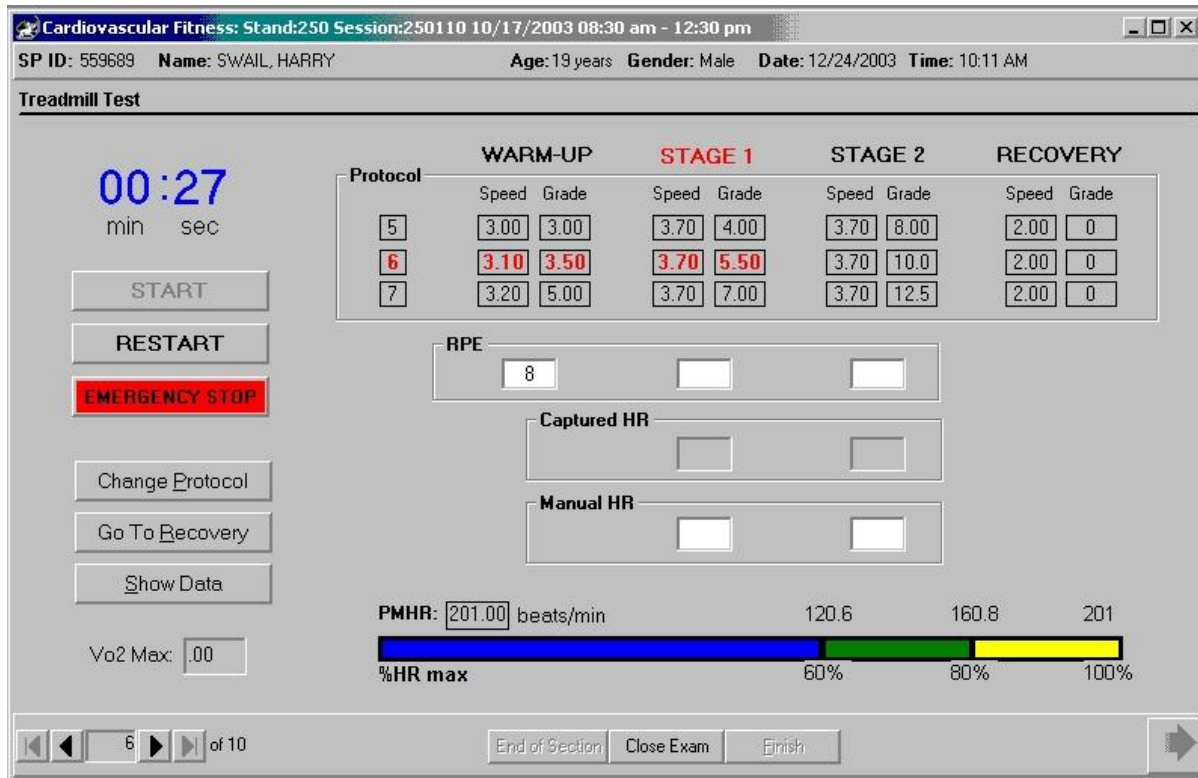
The screenshot displays the 'Cardiovascular Fitness' software interface for a treadmill test. At the top, it shows session information: 'Stand:250 Session:250110 10/17/2003 08:30 am - 12:30 pm'. Below this, patient details are listed: 'SP ID: 559689 Name: SWAIL, HARRY Age: 19 years Gender: Male Date: 12/24/2003 Time: 10:11 AM'. The main section is titled 'Treadmill Test' and features a large digital timer showing '00:22' (00 min, 22 sec). To the left of the timer are buttons for 'START', 'RESTART', and a red 'EMERGENCY STOP' button. Below these are 'Change Protocol', 'Go To Recovery', and 'Show Data' buttons. The 'Vo2 Max' field is set to '.00'. The central part of the screen contains a protocol table with columns for 'WARM-UP', 'STAGE 1', 'STAGE 2', and 'RECOVERY'. Each column has sub-columns for 'Speed' and 'Grade'. Protocol 7 is highlighted in red, showing a speed of 3.20 and a grade of 5.00. Below the table are 'RPE' and 'Manual HR' input fields. At the bottom, a heart rate monitor display shows 'PMHR: 201.00 beats/min' and a '%HR max' bar with markers at 50%, 60%, and 100%. The bar is currently at 50%. Navigation buttons at the bottom include 'End of Section', 'Close Exam', 'Finish', and a right arrow.

Protocol	WARM-UP		STAGE 1		STAGE 2		RECOVERY	
	Speed	Grade	Speed	Grade	Speed	Grade	Speed	Grade
6	3.10	3.50	3.70	5.50	3.70	10.0	2.00	0
7	3.20	5.00	3.70	7.00	3.70	12.5	2.00	0

- See Chapter 3, Section 3.7 for details on assignment of exercise protocol. Protocol 8 will not be used. If Protocol 8 is the assigned protocol, the SP will be re-assigned to Protocol 7. Protocol 8 will be grayed out on the ISIS screen.
- If the re-assigned protocol is 7 (the highest protocol in the current program) and the heart rate is less than 60 percent of PMHR during Warm-up, the protocol will remain unchanged due to the unavailability of the next higher protocol.

4.7 Emergency Stop

Exhibit 4-61. Emergency stop



- During the treadmill test you should monitor the SP constantly for any signs of discomfort or distress. If any of the conditions listed in the Priority 1 Stopping Criteria are present (or if for any other reason you think the test should be stopped immediately), follow the procedures for 'Emergency Stop.'
- Press 'Emergency Stop' on the ISIS screen. The ISIS system will go to Priority 1 Stopping Criteria and will give this auditory message:
"Press Cool Down on Treadmill Controller. Press Stop Belt."
- Press 'Cool Down' first. This will lower the grade on the treadmill. Then press Stop Belt. Assist the SP off the treadmill.
- Depending on the situation, you may call for assistance immediately when you notice signs of distress. If the situation is not critical but you want to terminate the test, follow the procedures and get the SP to the chair or floor and then get help. Try not to alarm the SP unnecessarily and maintain a calm, controlled atmosphere.
- Call the MEC physician and have the SP evaluated.
- When the situation is under control and the SP is stabilized, enter the appropriate information on the ISIS screens.

4.8 Priority 1 Stopping Criteria

Exhibit 4-62. Priority 1 stopping criteria - other

Cardiovascular Fitness Subsystem: Stand:806 Session:808559 12/10/1998 08:30 am - 12:30 pm

SP ID: 836308 Name: Anderson, Greg Age: 28 years Gender: Male Date: 01/03/1999 Time: 10:57 AM

Priority 1 Stopping Criteria

You have stopped the exam early. You must select one or more of the following stopping criteria:

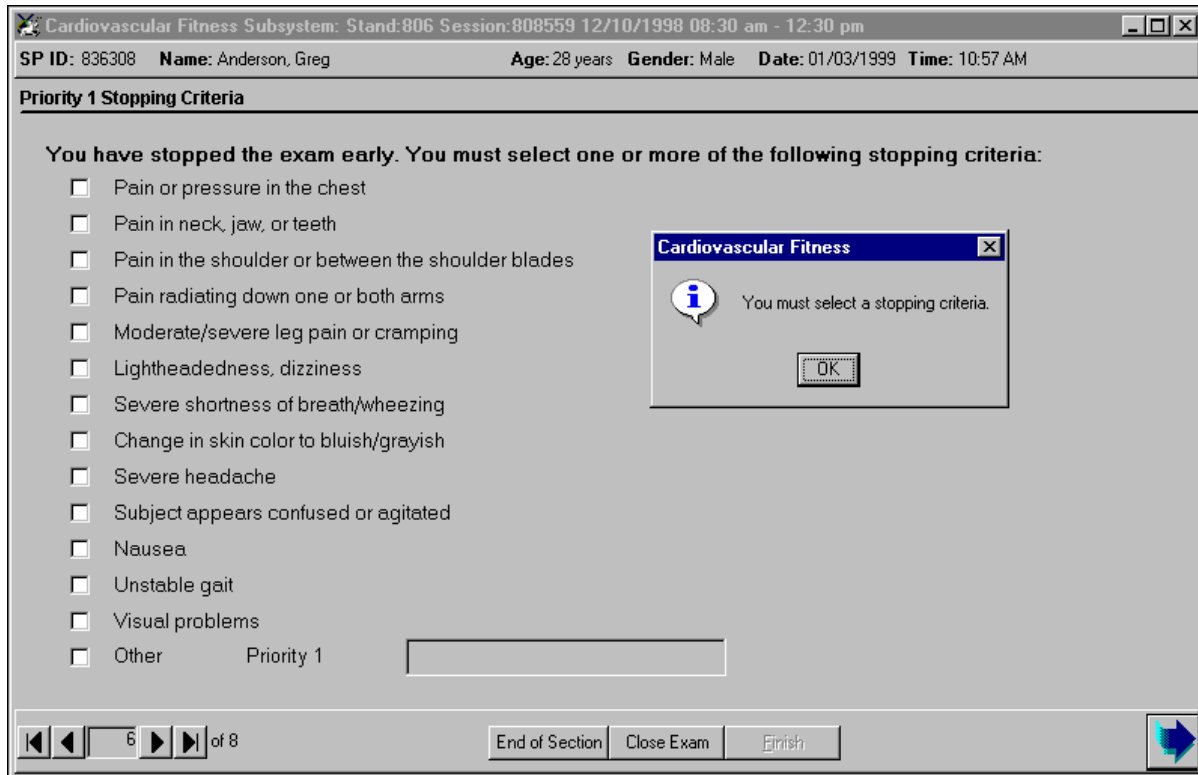
- Pain or pressure in the chest
- Pain in neck, jaw, or teeth
- Pain in the shoulder or between the shoulder blades
- Pain radiating down one or both arms
- Moderate/severe leg pain or cramping
- Lightheadedness, dizziness
- Severe shortness of breath/wheezing
- Change in skin color to bluish/grayish
- Severe headache
- Subject appears confused or agitated
- Nausea
- Unstable gait
- Visual problems
- Other Priority 1

6 of 8 End of Section Close Exam Finish

- If the 'Emergency Stop' button is pressed, the ISIS system will go immediately to Priority 1 Stopping Criteria. When the SP is stabilized and the situation is under control, check the appropriate reason for terminating the test for the criteria on the screen.
- The Priority 1 Stopping Criteria are:
 - Pain or pressure in the chest
 - Pain in the neck, jaw, or teeth
 - Pain in the shoulder or between the shoulder blades
 - Pain radiating down one or both arms
 - Moderate/severe leg pain or cramping
 - Lightheadedness, dizziness
 - Severe shortness of breath/wheezing
 - Change in skin color to bluish/grayish
 - Severe headache

- Subject appears confused or agitated
 - Nausea
 - Unstable gait
 - Visual problems
 - Other
- If you notice any or the above criteria or if the SP complains of any of the above, follow the procedures for 'Emergency Stop' and terminate the test immediately.

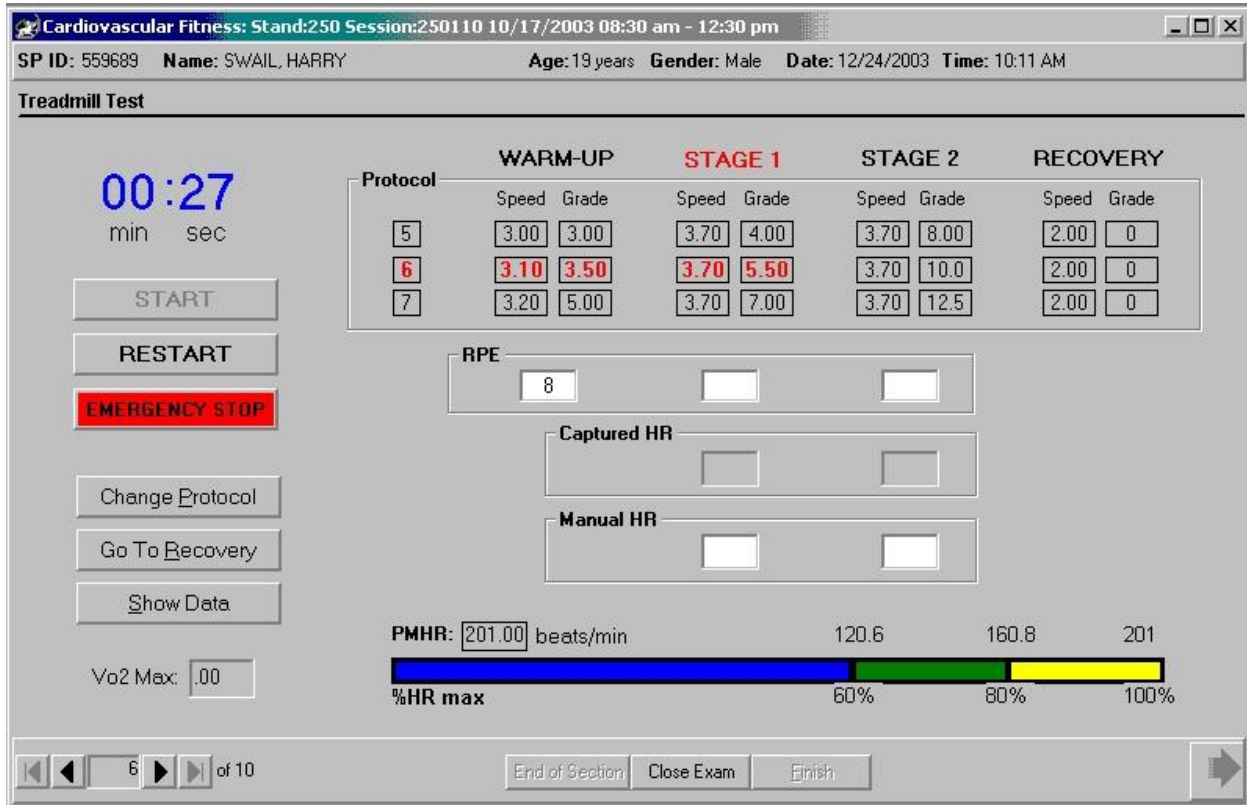
Exhibit 4-63. Priority 1 stopping criteria - required entry



- If the 'Emergency Stop' button is pressed, the Priority 1 Stopping Criteria screen appears. You are required to select one or more criteria.
- If you do not select a criterion and the Next button is pressed, the ISIS system will display a message: 'You must select a stopping criteria.'
- Click OK to this message. Select on or more criteria as appropriate and press the Next button to advance to the Component Status screen.
- The Component status will be set to 'Partial' with the comment 'Priority 1 Stopping Criteria.'
- Press the Finish button to close the exam.

4.9 Early Termination of Test – Go to Recovery

Exhibit 4-64. Go to recovery



- If any of the situations listed in 3.13.2 Priority 2 Stopping Criteria occur, the test should be terminated and moved to the Recovery stages. Some of the criteria are data related and the ISIS system will display a message that you should go to the Recovery Stage (See exhibits in 4.8.1 for examples). Other criteria will be noted by observation. You should be monitoring the SP closely for any signs of these criteria.
- If a Priority 2 Stop is warranted, Press ‘Go to Recovery’ on the ISIS screen.
- The ISIS system will then give an auditory message:
“Change treadmill controller to ‘Recovery Stage’ for current protocol.”
- Change the setting on the treadmill controller by pressing ‘Next Stage’ until the Recovery Stage is reached. Recovery stages 1 and 2 (and 3 if necessary) will be completed as usual. When Recovery is complete, press the ‘Next’ button to advance to the next screen.

4.9.1 Data Not Within Acceptable Limits

Some of the reasons for early termination included data items that exceed set limits.

There are edit limits set on the following measurements:

- Heart rate greater than 80 percent PMHR in Warm-up AND the SP is unable to continue.
- Heart rate greater than 85 percent PMHR (90% for 12 through 18 years) in any stage of the treadmill test AND the SP is unable to continue.
- Heart rate greater than 100 percent in any stage of the treadmill test.
- SBP greater than 260 mmHg.
- DBP greater than 115 mmHg.
- RPE greater than 17 (after confirming that the SP understands the concept).
- If these limits are exceeded, the ISIS system will display a message indicating what specific edit limits have been exceeded.

"(Data item) is not within acceptable limits. Go to Recovery."

- Click OK.
- The ISIS system will then give an auditory message:

"Press 'Go to Recovery' on ISIS screen."

"Change treadmill controller to Recovery Stage for current protocol."

- Change the setting on the treadmill controller by pressing Next Stage until the Recovery Stage is reached.
- Recovery Stages 1 and 2 (and 3 if necessary) will be completed as usual. When Recovery is complete, press the Next button to advance to the next screen.

Exhibit 4-65. Heart rate greater than specified criteria Warm-up (12 through 49 years)

The screenshot shows a software window titled "Cardiovascular Fitness: Stand:250 Session:250140 10/20/2003 08:30 am - 12:30 pm". The user information is: SP ID: 526725, Name: HART, JEFF, Age: 18 years, Gender: Male, Date: 12/29/2003, Time: 08:25 AM. The test is a "Treadmill Test" with a timer at 01:57. The protocol table is as follows:

Protocol	WARM-UP		STAGE 1		STAGE 2		RECOVERY	
	Speed	Grade	Speed	Grade	Speed	Grade	Speed	Grade
4	2.70	2.00	3.10	4.00	3.10	8.50	2.00	0
5	3.00	3.00	3.70	4.00	3.70	8.00	2.00	0
6	3.10	3.50	3.70	5.50	3.70	10.0	2.00	0

Below the table, the RPE is set to 14. A dialog box titled "Cardiovascular Fitness" is open, displaying the message: "Heart rate > 90% PMHR. If SP is OK, continue with test. If not, go to Recovery." with an "OK" button. At the bottom, the PMHR is 202.00 beats/min, and a progress bar shows %HR max at 50%, 60%, and 100%. The current heart rate is 101 and 131.3. The interface also includes buttons for "START", "RESTART", "EMERGENCY STOP", "End of Section", "Close Exam", and "Finish".

- If the heart rate is greater than 85 percent PMHR (90% PMHR for 12 through 18 years) during Warm-up determine if the SP is OK and able to continue. Monitor the SP closely throughout this stage and decrease the exercise protocol before starting Stage 1. When the data are captured at the end of the Warm-up, the ISIS system will display a message: 'Heart rate is greater than 85 percent PMHR (90%PMHR). If SP is OK, continue with the test. If not, go to Recovery.'
- Click OK.
- Decrease the exercise protocol and monitor the SP closely during the remainder of the treadmill test.

Exhibit 4-66. Heart rate greater than specified criteria Stage 1 (12 through 49 years)

The screenshot displays the 'Cardiovascular Fitness' software interface for a treadmill test. At the top, it shows 'SP ID: 109742', 'Name: MASON, JESSE', 'Age: 14 years', 'Gender: Male', 'Date: 12/24/2003', and 'Time: 11:16 AM'. The test is titled 'Treadmill Test' and shows a timer at 02:56. The protocol is divided into four stages: WARM-UP, STAGE 1, STAGE 2, and RECOVERY. Each stage has a table of Speed and Grade settings. A pop-up window titled 'Cardiovascular Fitness' is displayed, showing an information icon and the message: 'Heart rate > 80% PMHR. If SP is OK, continue with test. If not, go to Recovery.' Below the pop-up, the PMHR is listed as 206.00 beats/min. A progress bar at the bottom shows %HR max with markers at 60%, 80%, and 100%. The current HR is 168, which is above the 80% PMHR threshold. The interface also includes buttons for 'START', 'RESTART', 'EMERGENCY STOP', 'End of Section', 'Close Exam', and 'Finish'.

Protocol	WARM-UP		STAGE 1		STAGE 2		RECOVERY	
	Speed	Grade	Speed	Grade	Speed	Grade	Speed	Grade
5	3.00	3.00	3.70	4.00	3.70	8.00	2.00	0
6	3.10	3.50	3.70	5.50	3.70	10.0	2.00	0
7	3.20	5.00	3.70	7.00	3.70	12.5	2.00	0

- Ideally the HR should be between 60 to 80 percent PMHR during Warm-up for all age groups.
- If the heart rate is greater than 80 percent PMHR at any time during Stage 1 (for both age groups), determine if the SP is OK and able to continue the exam. If the SP is OK, continue with the test and monitor closely for the remainder of the exam. If the SP looks exhausted or does not want to continue, go to Recovery.
- When the data are captured at the end of Stage 1, the ISIS system will display a message: 'Heart rate is greater than 80 percent PMHR'. If SP is OK, continue with the test. If not, go to Recovery.'
- Click OK.

Exhibit 4-67. Heart rate greater than specified criteria Stage 2 (12 through 18 years)

The screenshot shows a software window titled "Cardiovascular Fitness: Stand:250 Session:250140 10/20/03". The user information is: SP ID: 526725, Name: HART, JEFF, Age: 18 years, Gender: Male, Date: 12/24/2003, Time: 10:52 AM. The test is a "Treadmill Test" with a timer showing 02:56 (min sec). On the left are buttons for START, RESTART, and EMERGENCY STOP. The protocol table is as follows:

Protocol	WARM-UP		STAGE 1		STAGE 2		RECOVERY	
	Speed	Grade	Speed	Grade	Speed	Grade	Speed	Grade
4	2.70	2.00	3.10	4.00	3.10	8.50	2.00	0
5	3.00	3.00	3.70	4.00	3.70	8.00	2.00	0
6	3.10	3.50	3.70	5.50	3.70	10.0	2.00	0

Below the protocol table are RPE values: 11, 14, 17. Captured HR values are 150 and 184. A dialog box is open with the message: "Heart rate > 90% PMHR. If SP is OK, continue with test. If not, go to Recovery." with an OK button. At the bottom right, a %HR max bar shows 181.8 (90%) and 202 (100%). Navigation buttons at the bottom include "End of Section", "Close Exam", and "Finish".

- Ideally the HR should be below 90 percent for 12- through 18-year-olds
- If the heart rate is greater than 90 percent PMHR for 12 through 18 years at any time during Stage 2 determine if the SP is OK and able to continue the exam. If the SP is OK, continue with the test and monitor closely for the remainder of the exam. If the SP looks exhausted or does not want to continue, go to Recovery.
- When the data are captured at the end of Stage 2, the ISIS system will display a message: 'Heart rate is greater than 90 percent PMHR. If SP is OK, continue with the test. If not, go to Recovery.'
- Click OK.

Exhibit 4-68. Heart rate greater than specified criteria Stage 2 (19 through 49 years)

The screenshot shows a software window titled "Cardiovascular Fitness: Stand:250 Session:250110:10:10". The user information is: SP ID: 592366, Name: GAINES, BILLY, Age: 38 years, Gender: Male, Date: 12/24/2003, Time: 10:28 AM. The test is a "Treadmill Test" with a timer at 02:57 (02 min, 57 sec). The interface is divided into four stages: WARM-UP, STAGE 1, STAGE 2, and RECOVERY. Each stage has a protocol table with Speed and Grade settings. Protocol 6 is highlighted in red, indicating it is the current stage. The RPE (Rating of Perceived Exertion) is shown as 9, 13, and 16 for the respective stages. A "Captured HR" section shows 146 and 157. A "%HR max" bar chart shows the current heart rate at 154.7, which is above the 85% threshold (153.75) and below the 100% threshold (182). A dialog box is open with the message: "Heart rate > 85% PMHR. If SP is OK, continue with test. If not, go to Recovery." The dialog has an "OK" button. The bottom of the window shows navigation controls, including "End of Section", "Close Exam", and "Finish" buttons.

Protocol	WARM-UP		STAGE 1		STAGE 2		RECOVERY	
	Speed	Grade	Speed	Grade	Speed	Grade	Speed	Grade
5	3.00	3.00	3.70	4.00	3.70	8.00	2.00	0
6	3.10	3.50	3.70	5.50	3.70	10.0	2.00	0
7	3.20	5.00	3.70	7.00	3.70	12.5	2.00	0

- Ideally the HR should be below 85 percent PMHR for SPs 19 through 49 years.
- If the heart rate is greater than 85 percent PMHR for this age group at any time during Stage 2 determine if the SP is OK and able to continue the exam. If the SP is OK, continue with the test and monitor closely for the remainder of the exam. If the SP looks exhausted or does not want to continue, go to Recovery.
- When the data are captured at the end of Stage 2, the ISIS system will display a message: 'Heart rate is greater than 85 percent PMHR. If SP is OK, continue with the test. If not, go to Recovery.'
- Click OK.

Exhibit 4-69. Heart rate greater than 100 percent during any stage (12 through 49 years)

The screenshot displays the Cardiovascular Fitness software interface for a treadmill test. At the top, it shows the session ID (863711), name (HART, CINDY), age (34 years), gender (Female), date (12/24/2003), and time (11:21 AM). The test is titled "Treadmill Test" and shows a timer at 02:57. The protocol is divided into four stages: WARM-UP, STAGE 1, STAGE 2, and RECOVERY. Each stage has a table of Speed and Grade values. A warning message is displayed, stating "Heart rate > 100% PMHR. Heart Rate is not within acceptable limits. Go to RECOVERY." The interface also shows RPE values (12, 14, 17), Captured HR values (160, 190), and a %HR max bar graph showing 85% of the maximum heart rate (PMHR: 186.00 beats/min).

Protocol	WARM-UP		STAGE 1		STAGE 2		RECOVERY	
	Speed	Grade	Speed	Grade	Speed	Grade	Speed	Grade
3	2.20	2.00	2.70	3.00	2.70	7.50	2.00	0
4	2.70	2.00	3.10	4.00	3.10	8.50	2.00	0
5	3.00	3.00	3.70	4.00	3.70	8.00	2.00	0

- The heart rate should never be greater than 100 percent PMHR
- If the heart rate is greater than 100 percent PMHR at any time during the test, go to the Recovery stage.
- If the HR is greater than 100 percent PMHR when the data is captured at the end of any stage, the ISIS system will display a message: 'Heart rate is greater than 100 percent PMHR. Heart rate is not within acceptable limits. Go to Recovery.'
- Click OK. Follow the steps outlined above at the beginning of this section.

Exhibit 4-70. SBP not within acceptable limits

The screenshot displays the Cardiovascular Fitness software interface for a Treadmill Test. The window title is "Cardiovascular Fitness: Stand:250 Session:250140 10:20". The patient information at the top includes: SP ID: 163691, Name: HART, JEANNIE, Age: 33 years, Gender: Female, Date: 12/24/2003, Time: 10:44 AM. The test is titled "Treadmill Test" and shows a timer at 02:55 (min sec). On the left, there are buttons for START, RESTART, EMERGENCY STOP, Change, Go, and Show Data. The main area contains a protocol table with columns for WARM-UP, STAGE 1, STAGE 2, and RECOVERY, each with Speed and Grade settings. A pop-up message box titled "Cardiovascular Fitness" is displayed, stating "SBP is not within acceptable limits. Go to RECOVERY." with an OK button. Below the protocol table, there are input fields for RPE (11) and HR (130). At the bottom, there is a PMHR display (187.00 beats/min) and a %HR max bar chart showing 60%, 80%, and 100% markers. The bottom status bar shows "6 of 10" and buttons for "End of Section", "Close Exam", and "Finish".

Protocol	WARM-UP		STAGE 1		STAGE 2		RECOVERY	
	Speed	Grade	Speed	Grade	Speed	Grade	Speed	Grade
3	2.20	2.00	2.70	3.00	2.70	7.50	2.00	0
4	2.70	2.00	3.10	4.00	3.10	8.50	2.00	0
5	3.00	3.00	3.70	4.00	3.70	8.00	2.00	0

- If the systolic blood pressure is greater than 260 mmHG at any time during Warm-up, Stage 1 or Stage 2, the ISIS system will display a message: ‘SBP is not within acceptable limits. Go to Recovery.’
- Click OK. Follow the steps outlined above at the beginning of this section.

Exhibit 4-71. DBP not within acceptable limits

The screenshot shows the 'Cardiovascular Fitness' software interface. At the top, it displays 'SP ID: 163691 Name: HART, JEANNIE Age: 33 years Gender: Female Date: 12/24/2003 Time: 10:44 AM'. Below this is the 'Treadmill Test' section. On the left, a large digital clock shows '02:57' with 'min' and 'sec' labels. Below the clock are buttons for 'START', 'RESTART', 'EMERGENCY', 'Change', 'Go To B', and 'Show Data'. The main area contains a protocol table with columns for 'WARM-UP', 'STAGE 1', 'STAGE 2', and 'RECOVERY', each with sub-columns for 'Speed' and 'Grade'. A 'RPE' section has input fields for '12' and '15'. At the bottom, there is a 'PMHR' section with a value of '187.00' and a '%HR max' bar chart with markers at 60%, 80.6%, and 100%. A dialog box is overlaid on the screen with the title 'Cardiovascular Fitness' and the message 'DBP is not within acceptable limits. Go to RECOVERY.' with an 'OK' button.

Protocol	WARM-UP		STAGE 1		STAGE 2		RECOVERY	
	Speed	Grade	Speed	Grade	Speed	Grade	Speed	Grade
3	2.20	2.00	2.70	3.00	2.70	7.50	2.00	0
4	2.70	2.00	3.10	4.00	3.10	8.50	2.00	0
5	3.00	3.00	3.70	4.00	3.70	8.00	2.00	0

PMHR: 187.00 beats/min

%HR max: 60% 80.6% 100%

- If the diastolic blood pressure is greater than 115 mmHG at any time during Warm-up, Stage 1 or Stage 2, the ISIS system will display a message: 'DBP is not within acceptable limits. Go to Recovery.'
- Click OK. Follow the steps outlined above at the beginning of this section.

Exhibit 4-72. Rating of perceived exertion not within acceptable limits

The screenshot shows the Cardiovascular Fitness software interface. At the top, it displays the session information: SP ID: 163691, Name: HART, JEANNIE, Age: 33 years, Gender: Female, Date: 12/24/2003, Time: 10:44 AM. The main window is titled "Treadmill Test" and shows a timer at 02:44 (min sec). Below the timer are buttons for START, RESTART, and EMERGENCY STOP. A protocol table is displayed with columns for WARM-UP, STAGE 1, STAGE 2, and RECOVERY, each with Speed and Grade settings. The RPE (Rating of Perceived Exertion) is shown as 15 and 19. A warning message box is open, stating "RPE is above acceptable criteria, go to recovery." Below the message box, there are input fields for PMHR (187.00 beats/min) and %HR max (60%, 80%, 100%). The interface also includes navigation buttons at the bottom: End of Section, Close Exam, and Finish.

Protocol	WARM-UP		STAGE 1		STAGE 2		RECOVERY	
	Speed	Grade	Speed	Grade	Speed	Grade	Speed	Grade
3	2.20	2.00	2.70	3.00	2.70	7.50	2.00	0
4	2.70	2.00	3.10	4.00	3.10	8.50	2.00	0
5	3.00	3.00	3.70	4.00	3.70	8.00	2.00	0

RPE: 15, 19

PMHR: 187.00 beats/min

%HR max: 60%, 80%, 100%

- If the Rating of Perceived Exertion (RPE) is greater than 17 at any time during Warm-up, Stage 1 or Stage 2, the ISIS system will display a message: 'RPE is not within acceptable limits. Go to Recovery.'
- Click OK. Follow the steps outlined above at the beginning of this section.

4.10 Priority 2 Stopping Criteria

Exhibit 4-73. Priority 2 stopping criteria

The screenshot shows a software window titled "Cardiovascular Fitness: Stand:250 Session:250100 10/16/2003 08:30 am - 12:30 pm". The window contains the following information:

SP ID: 308832 Name: SATO, YOUME Age: 28 years Gender: Female Date: 12/29/2003 Time: 11:00 AM

Priority 2 Stopping Criteria

You have stopped the exam early. You must select one or more of the following stopping criteria:

- SP HR during Warm-up, Stage 1 or Stage 2 exceeds 90 percent for 12- through 18-year-olds or 85 percent PMHR for 19- through 49-year-olds and SP is unable to continue.
- SP HR exceeds 80 percent PMHR during Stage 1 and SP is unable to continue.
- SP HR exceeds 100% during Warm-up, Stage 1 or Stage 2
- Exercise blood pressure > 260 mmHg systolic and/or 115 mmHg diastolic
- Failure of systolic blood pressure to rise with increasing exercise intensity
- Significant drop (>20 mmHg) in systolic blood pressure during exercise
- Failure of heart rate to increase with increasing exercise intensity
- Sudden, noticeable variability in heart rate (sudden change of + 30 beats/minute during a STAGE)
- SP requests to stop test, or reports severe fatigue
- Failure of testing equipment
- SP is unable to stop gripping hand rails
- SP reports RPE > 17
- Technician discretion (tech notices signs of severe exertion).
- Other Enter Comment:

At the bottom of the window, there are navigation buttons: "End of Section", "Close Exam", and "Finish". A "Next" button is also visible on the right side. The status bar at the bottom indicates "8 of 10".

- If the treadmill test is terminated early due to one or more of the Priority 2 Stopping Criteria, the SP will go to the Recovery Stage of the current protocol.
- After completing the normal cool-down, the ISIS system will advance to the Priority 2 Stopping Criteria screen.
- Select one or more of the appropriate stopping criteria.
- You are required to select one or more of these criteria if 'Go to Recovery' was selected on the previous screen.
- If you do not select a criterion, the ISIS system will display a message when the Next button is selected: 'You must select a stopping criterion.'
- Click OK. Select one or more of the criteria and press the Next button to advance to the next screen.

Exhibit 4-74. Component status for priority 2

Cardiovascular Fitness Subsystem: Stand:806 Session:808571 12/11/1998 05:30 pm - 09:30 pm

SP ID: 553247 Name: Adams, Henry Age: 44 years Gender: Male Date: 01/24/1999 Time: 05:58 PM

Cardiovascular Fitness Component Status

Status

Complete

Partial

Not Done

Comments: Priority 2 stopping criteria

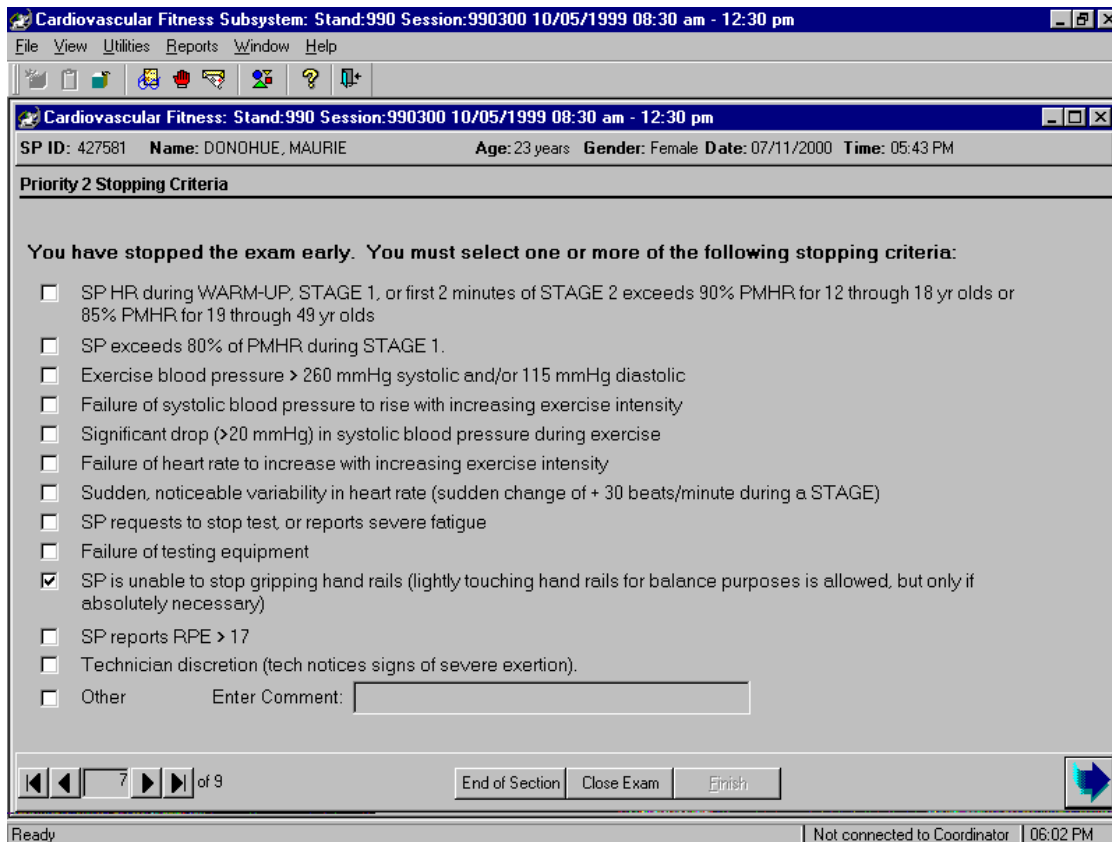
Other text: _____

8 of 8

End of Section Close Exam Finish

- The ISIS system will advance to the Component Status Screen.
- The Component Status will be set to 'Partial.'
- The comment will be set to 'Priority 2 Stopping Criteria'.
- Press the 'Finish' button to close the exam.
- The ISIS system will not calculate the VO2 max.

Exhibit 4-75. SP unable to stop gripping handrails



- SP's are required to walk on the treadmill without holding on to the handrail. Grasping the handrail throughout the test will tend to overestimate the SP's VO₂ max.
- Some SP's may hold the handrail for support at the beginning of the exam for support. If this occurs, repeat the instructions for walking on a treadmill and try to coach him or her to walk on the treadmill without holding. Remind the SP to stand up straight, look ahead not down at their feet and take long steps as the belt moves.
- Lightly touching the handrails for balance purposes is allowed but only if absolutely necessary.
- Give them lots of encouragement and try to keep the SP walking on the belt. If they continue to have problems and are holding on or briefly grabbing the handrails after you have repeated these instructions, use the method for stopping the test early and go to Recovery.
- Do not allow the SP to complete the exam if he or she is holding on to the handrails for a large part of the test as this will result in an overestimation of the VO₂ max.
- After the Recovery stage is completed, the ISIS system will advance to the Priority 2 Stopping Criteria.
- Select 'SP is unable to stop gripping handrails.' See Exhibit 4-72.

4.11 Combination of Priority 1 & 2 Stopping Criteria

On occasion, the test may be stopped initially for a Priority 2 Stopping criterion such as heart rate above acceptable limits and the SP is unable to continue. The technician selects Go to Recovery and the treadmill controller is put in the Recovery Stage. At any time during the Recovery Stages the test may need to be stopped due to a Priority 1 Stopping criterion such as dizziness, nausea, or severe leg cramps. The technician would then select Emergency Stop to end the test immediately and select Cool Down and Stop Belt on the treadmill controller. The Priority 1 screen will be displayed but the Priority 2 screen will not be displayed. The technician must enter the complete information about the reasons for stopping the test on the Priority 1 Stopping Criteria screen. The way to do this is:

Exhibit 4-76. Data entry for combination of Priority 1 and 2 criteria

Cardiovascular Fitness: Stand:250 Session:250140 10/20/2003 08:30 am - 12:30 pm

SP ID: 770676 Name: FOX, BRUCE Age: 27 years Gender: Male Date: 12/27/2003 Time: 02:37 PM

Priority 1 Stopping Criteria

You have stopped the exam early. You must select one or more of the following stopping criteria:

- Pain or pressure in the chest
- Pain in neck, jaw, or teeth
- Pain in the shoulder or between the shoulder blades
- Pain radiating down one or both arms
- Moderate/severe leg pain or cramping
- Lightheadedness, dizziness
- Severe shortness of breath/wheezing
- Change in skin color to bluish/grayish
- Severe headache
- Subject appears confused or agitated
- Nausea
- Unstable gait
- Visual problems
- Other Enter Comment: PR2 HR>85%

7 of 10 End of Section Close Exam Finish

- Check the appropriate box for the reason for going to an Emergency Stop (eg. dizziness)
- Check Other and enter a comment in the text field to indicate why Go to Recovery was selected.
- If the reason for going to the Recovery Stage was the heart rate enter the following abbreviated comment in the text field: “PR2 HR>85% Stg2”
- This will indicate that the SPs heart rate was greater than 85 percent in Stage 2 and the SP was unable to continue so Go to Recovery was selected.

4.12 Problems With Data Acquisition During Treadmill Test

There are several potential sources for problems with acquisition of data during the treadmill test. After the test is completed a screen will be displayed to allow entry of problems that may occur during the test with equipment, integration, and technician error. You are able to check all that apply. It is extremely important to check off the correct problem.

Exhibit 4-77 - Problems with data acquisition - No problems

Cardiovascular Fitness: Stand:703 Session:703360 04/09/1999 08:30 am - 12:30 pm

SP ID: 618864 Name: PARKER, JACK Age: 21 years Gender: Male Date: 08/14/1999 Time: 07:15 AM

Problems with data acquisition during treadmill test

No Problem

Problem obtaining BP - BP not displayed on the BP monitor, not captured in ISIS:

BP not obtained in Baseline BP not obtained in Warmup BP not obtained in Stage 1

BP not obtained in Stage 2 BP not obtained in Recovery 1, 2, and /or 3

Other

Problem with data capture - BP displayed correctly on STBP monitor but not correctly captured in ISIS

BP on STBP OK, not captured in ISIS BP displayed normally on BP monitor, different data captured in ISIS

Other

Problem obtaining HR

Too much variability on HR on monitor to determine accurate HR

Other

Problem with electrodes

adherence problem due to excessive perspiration adherence problem due to excessive chest hair

large chest/abdomen Other

Problem with BP cuff

large arm caused difficulty with microphone placement cuff slipped off during test

SP bending/flexing arm during test Other

Problem with treadmill controller

Controller advanced more than one stage - Restarted test Other

8 of 9

End of Section Close Exam Finish

- **No Problem** - If there have been no problems with data acquisition during the test, check 'No Problem.' The remaining fields on the screen will be disabled. If you try to advance to the next screen without checking a problem or 'No problem,' the ISIS system will display a message to remind you to check this.

Exhibit 4-78. Problems with data acquisition - BP, data capture, and HR

- **Problem obtaining BP - BP not displayed on the BP monitor, not displayed in ISIS** - This problem can occur for several reasons. If the BP cuff is not positioned correctly on the arm, if the SP has a large arm and the signal to the microphone is not reaching the microphone, or if the SP is bending or flexing the arm at the time of data acquisition, select this option. When this problem occurs, the technician should check the position of the microphone. This problem can occur in one or all stages of the treadmill test. If this occurs at the pretest measurement, you should reposition the cuff and recapture the BP. You should always get a pretest BP before starting the test.
- **Problem with data capture - BP not displayed correctly on BP monitor** - This is not a problem with cuff position or the BP monitor. This is a problem with the transfer of data from the BP monitor to the ISIS system. This may be caused by interference with the data transfer from an outside source. If this happens, check the connections of the BP monitor to the computer and to the power source at every connection. The BP monitor should be on a different circuit than the treadmill. This could also be a problem with the ISIS system in receiving the data transfer.
- **Problems obtaining HR** - This can occur if there is something interfering with the electrodes picking up the signal. This can be caused by such things as inadequate preparation of the skin, poor placement of the electrodes, perspiration, chest hair interfering with the adherence of the electrode to the skin, an irregular heart rate, faulty electrodes, leads, or cables. If this occurs, troubleshoot to determine the cause.

Exhibit 4-79. Problems with data acquisition - electrodes, BP cuff, and treadmill controller

- **Problem with electrodes** - Causes of problems with electrodes include inadequate skin preparation, chest hair, faulty electrodes, and a large chest or abdomen.
- **Problem with BP cuff** - The SP may have a large arm that makes the positioning of the cuff difficult. If the cuff is not attached snugly to the arm, it may slip during the exam. In addition, if the SP is flexing when the cuff is applied, the cuff may slip out of position when the arm is relaxed. Bending or flexing the arm may also cause some problems. The SP should be encouraged to let his or her arm hang in a relaxed manner and should avoid extreme flexing although they do not have to hold their arms in a stiff uncomfortable position.
- **Problem with treadmill controller** - If the buttons on the treadmill are inadvertently pushed in error, the test may be restarted if this occurs before the first 15 seconds in Stage 1. If this happens after warm-up when changing protocols or going to recovery, you have the option of going to the next set of protocols on the controller.
- Check all data acquisition problems that apply. Be very careful that the selection you make accurately describes the problem you had.

4.13 Component Status Categories

4.13.1 Complete

Exhibit 4-80. Component status - complete

The screenshot displays a Windows-style application window titled "Cardiovascular Fitness Subsystem: Stand:703 Session:703360 04/09/1999 08:30 am - 12:30 pm". The window has a menu bar with "File", "View", "Utilities", "Reports", "Window", and "Help". Below the menu bar is a toolbar with various icons. The main content area is titled "Cardiovascular Fitness Component Status" and contains a dialog box with the following elements:

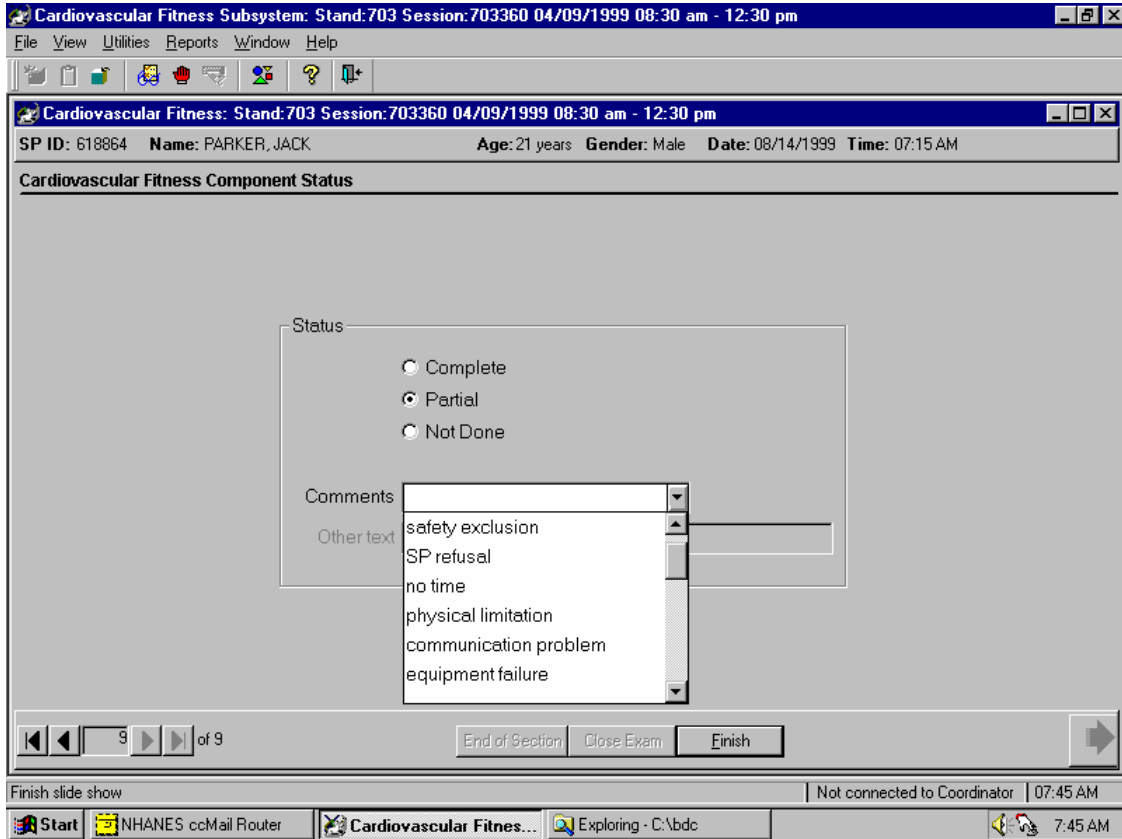
- A "Status" label above a group box containing three radio buttons:
 - Complete
 - Partial
 - Not Done
- A "Comments" label followed by a text input field and a dropdown arrow.
- An "Other text" label followed by a larger text input field.

At the bottom of the dialog box, there are navigation buttons: "End of Section", "Close Exam", and "Finish". The main window also has a status bar at the bottom with "Ready", "Not connected to Coordinator", and "07:40 AM". The Windows taskbar at the very bottom shows the Start button, several open applications (NHANES ccMail R..., Cardiovascular..., Exploring - C:\bdc, cv2.wav - Sound...), and the system clock showing 7:41 AM.

- Component status is set by the ISIS system as complete, partial, or not done. If all data were collected and entered, the system will set the status to complete.

4.13.2 Partial

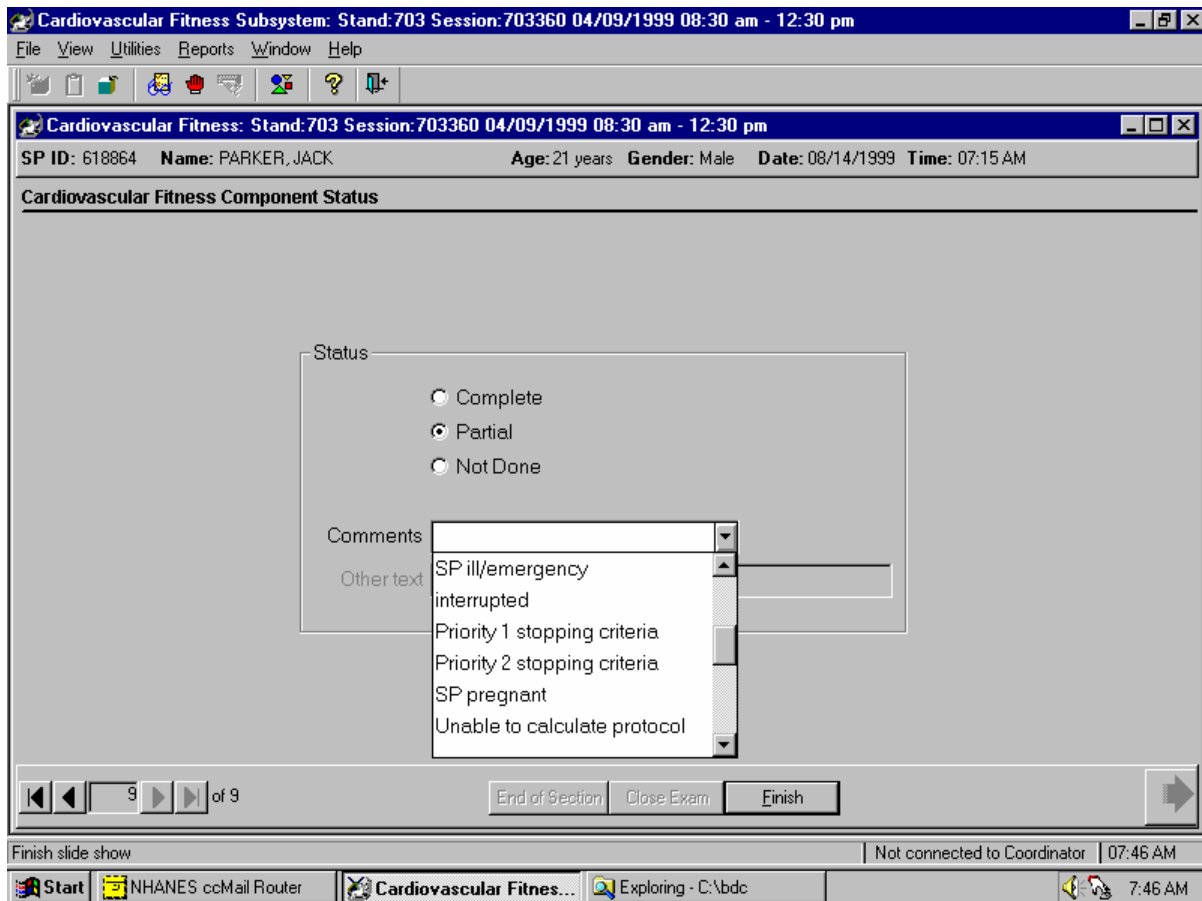
Exhibit 4-81. Component status - partial (1)



- If one or more pieces of data are missing (RPE measurement, blood pressure, PAR questions), the status will be set to partial.
- If the component status is partial, a comment is required. In some situations, the comment will be set to default. The comments that may be selected are listed below with a description of the situation where this comment is applicable. See Exhibit 4-78.
 - **Safety exclusion.** The SP is excluded from the exam due to a medical condition, current medications, or other situation that might cause the SP harm. The technician should not have to select this comment after the SP is in the CV Room because all the safety exclusion checks are completed prior to being assigned to this component. This would be set by the coordinator or physician applications.
 - **SP refusal.** The SP refused to do the exam.
 - **No time.** There was not sufficient time in the session to complete this exam.

- **Physical limitation.** The SP has a physical limitation that would prevent him/her from doing the exam. The technician should not have to select this comment after the SP is in the CV Room because all the physical limitation checks are completed prior to being assigned to this component. This would be set as default by the coordinator or physician applications.
- **Equipment failure.** The equipment malfunctioned making it impossible to complete the exam. This will not be selected because more specific information will be collected from the data acquisition screen.
- **Interrupted.** The exam or session had to be interrupted due to an emergency in this room or other area in the MEC making it impossible to complete the exam.

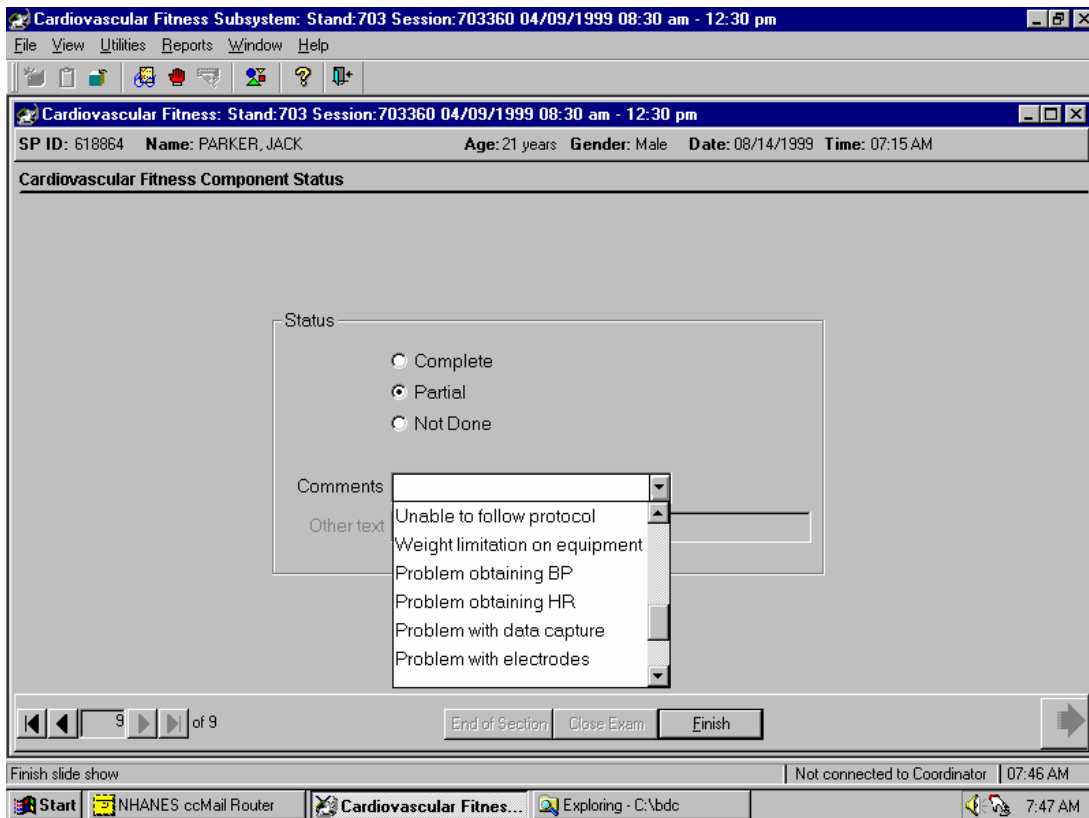
Exhibit 4-82. Component status - partial (2)



Other comments for 'partial' include:

- **Priority 1 Stopping Criteria.** The treadmill test was stopped early due to one or more of these criteria. See Section 3.13.1.
- **Priority 2 Stopping Criteria.** The treadmill test was stopped early due to one or more of these criteria. (Recovery Stages completed). See Section 3.13.2.
- **Protocol change.** The protocol was increased or decreased.
- **SP pregnant.** The SP was more than 12 weeks pregnant. See Section 3.1.1.
- **Unable to calculate protocol.** The ISIS system was unable to calculate the protocol because the data for height and weight for PAR Code data were not entered.

Exhibit 4-83. Component status - partial (3)



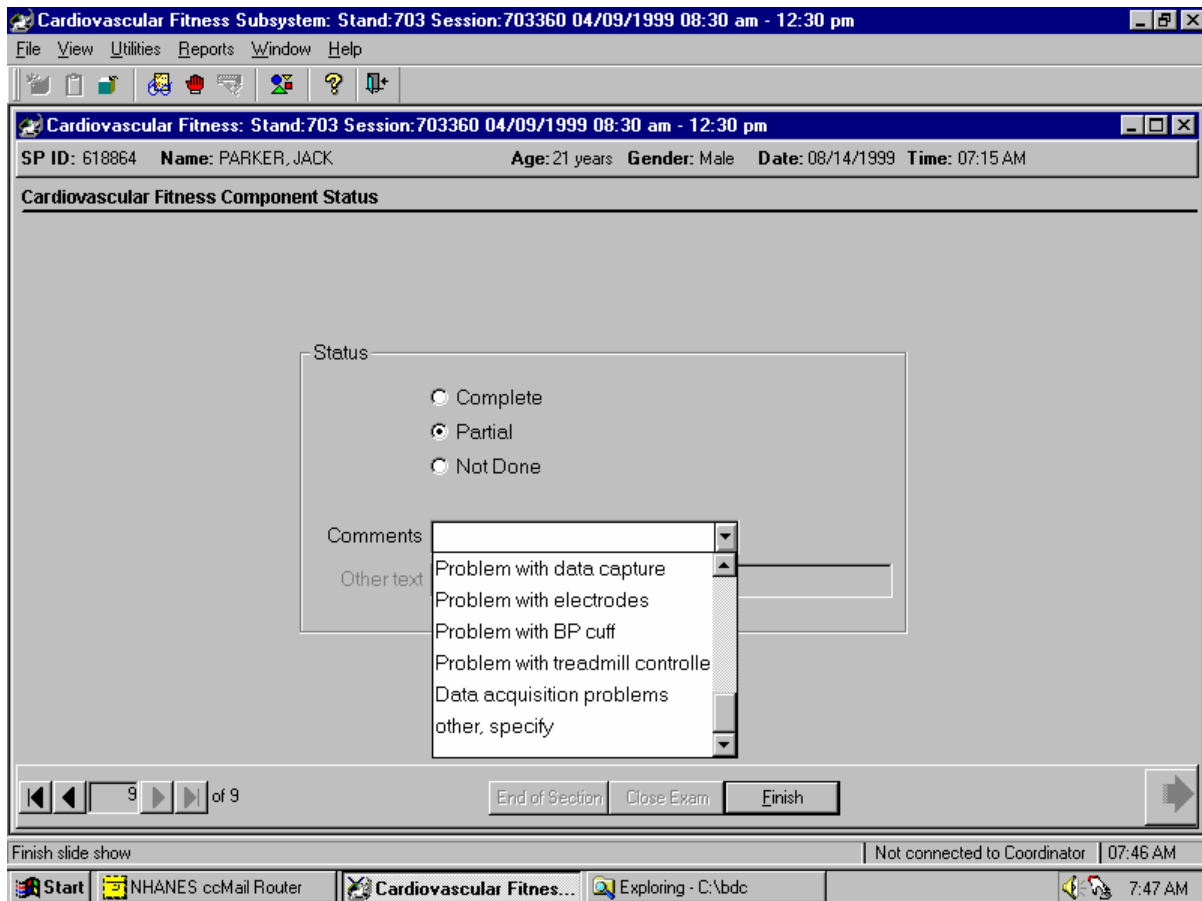
Other comments for 'partial' include:

- **Unable to follow protocol.** The SP is unable to follow the directions for walking on the treadmill and are unable to get accustomed to the exercise.
- **Weight limitation on equipment.** The weight limitation on the treadmill is 400 pounds. If the weight is greater than 350 pounds, SPs are excluded from this exam.

The following comments will be selected on the data acquisition screen and are described in Section 4-10. If one or more of these problems are selected in the data acquisition screen, the comment 'data acquisition' will be set to default for this comment field.

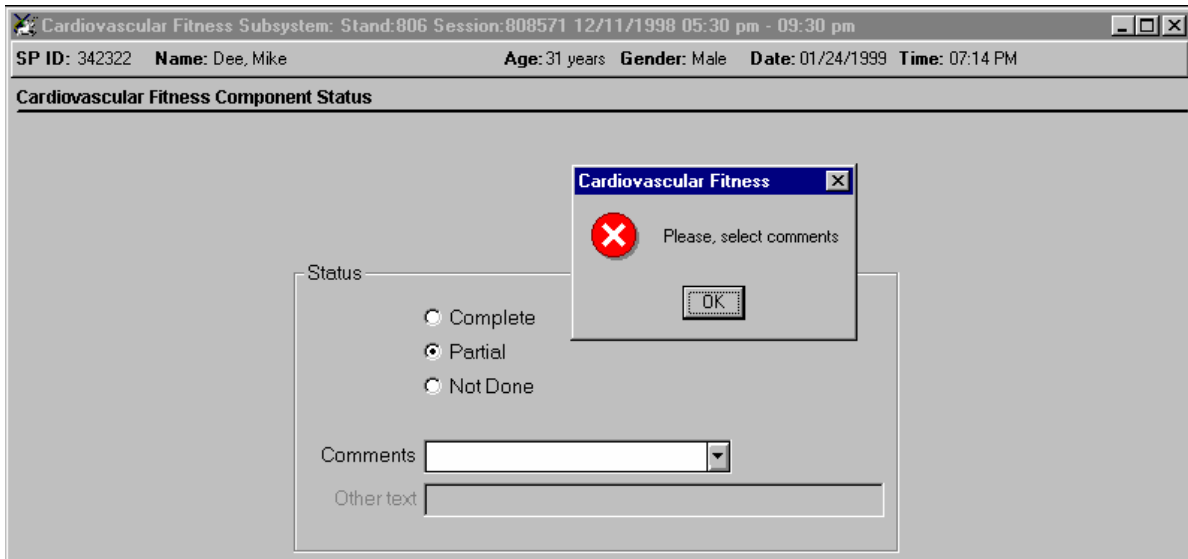
- **Problem obtaining BP** – data acquisition problem set to default
- **Problem obtaining HR** – data acquisition problem set to default
- **Problem with data capture** – data acquisition problem set to default
- **Problem with electrodes** – data acquisition problem set to default
- **Problem with BP cuff** – data acquisition problem set to default
- **Problem with BP controller** – data acquisition problem set to default

Exhibit 4-84. Component status – partial (4)



- **Data acquisition problems.** If one or more of the problems selected on the data acquisition screen are selected, 'data acquisition problems' will be selected as the default comment. The specific information about the problem can be obtained from the data acquisition screen, which allows multiple entries as opposed to the comments for component status which allow only one comment to be selected.
- **Other.** Other situations that cause the SP to be excluded from this exam at some point during the exam should be noted.

Exhibit 4-85. Component status - partial - required comments



- If a comment is not selected from the drop-down menu, a message will be displayed: 'Please select comments.'

4.13.3 Not Done

Exhibit 4-86. Component status - not done

Cardiovascular Fitness Subsystem: Stand:806 Session:808571 12/11/1998 05:30 pm - 09:30 pm

File View Utilities Reports Window Help

Cardiovascular Fitness Subsystem: Stand:806 Session:808571 12/11/1998 05:30 pm - 09:30 pm

SP ID: 977952 Name: Ball, Britney Age: 37 years Gender: Female Date: 01/24/1999 Time: 07:26 PM

Cardiovascular Fitness Component Status

Status

Complete

Partial

Not Done

Comments

Other text

safety exclusion

SP refusal

no time

physical limitation

communication problem

equipment failure

SP ill/emergency

8 of 8

End of Section Close Exam Finish

Finish slide show

- The comments for 'Not Done' are the same as for 'partial.'

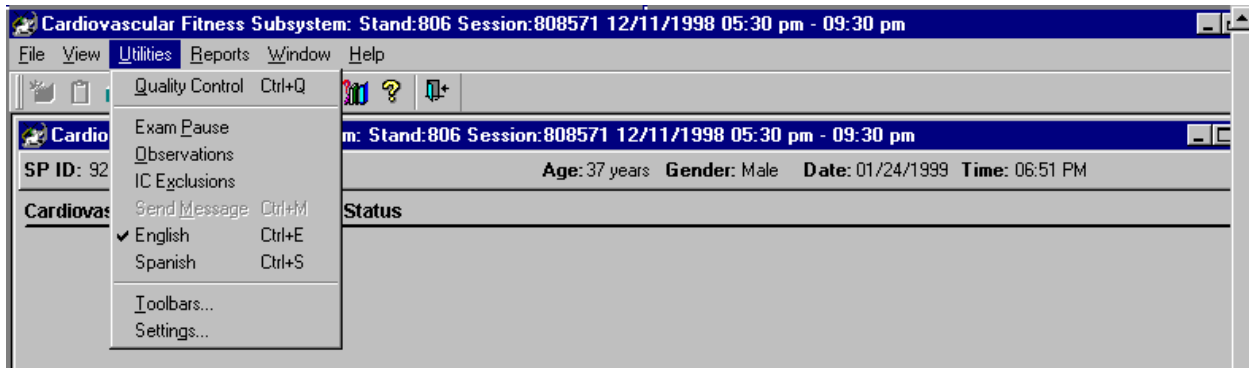
5. REFERRALS AND REPORT OF FINDINGS

5.1 Observation Referrals

Observation referrals are nonemergency situations that may arise in any of the examination rooms in the MEC. Technologists may send an observation referral to the MEC physician if they notice any condition that may be abnormal or that may warrant further assessment. This type of referral may be sent at any time from any of the exam rooms. The referral may or may not have anything to do with the current exam being performed.

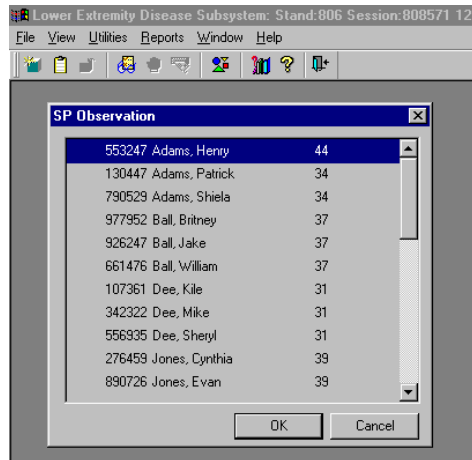
Once a technologist sends a referral to the physician, the Integrated Survey Information System (ISIS) will flag the referral for the SP in the Physician Referral Review Box. (ISIS is the data entry system that will be used in this study; see Section 1.3 for a brief description.) The SP will not be checked out of the MEC until the physician has reviewed this referral. The physician will make a decision whether further action is warranted and a physician referral to the SP's health care provider may be given to the SP.

Exhibit 5-1. Menu to select observation referral



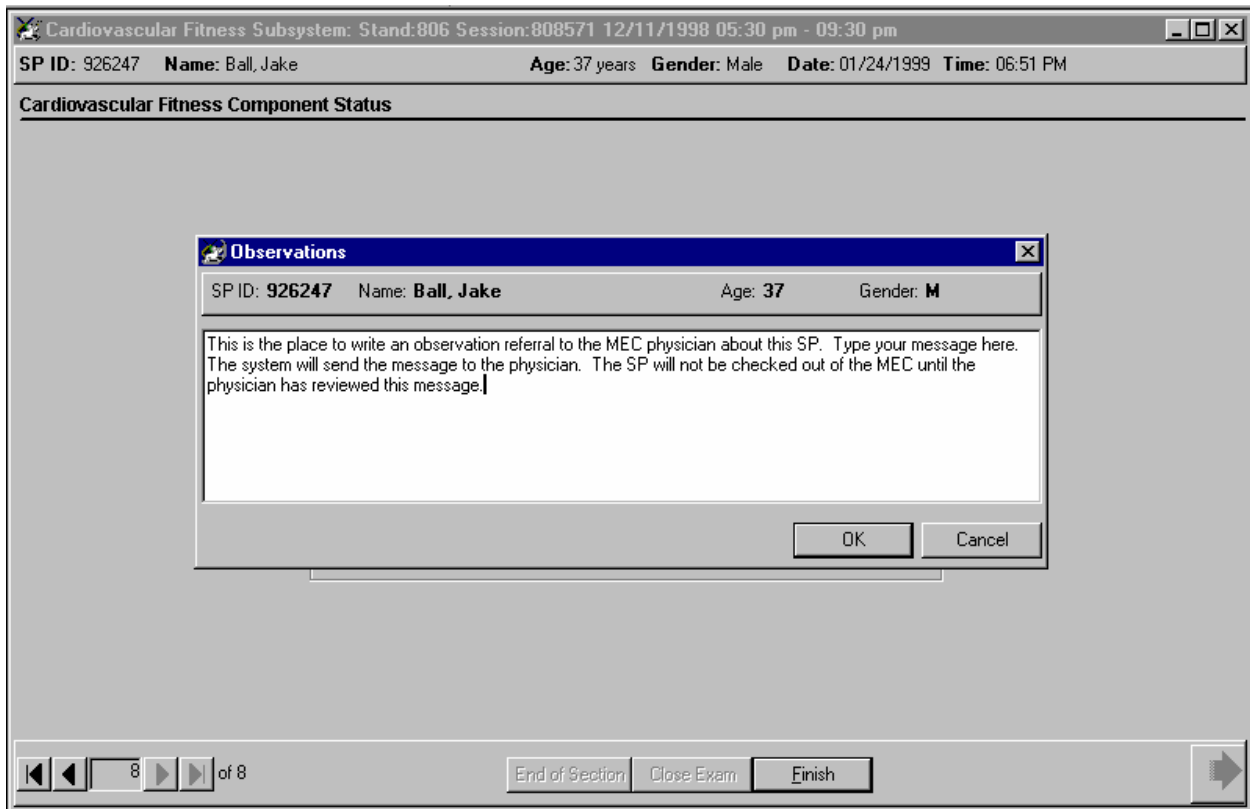
- Observation referrals can be sent during the exam or after the exam has been closed.
- Under 'Utilities,' select 'Observations.' If an exam is already opened, the observation referral box for that SP will be displayed. See Exhibit 5-1.
- If the exam has been closed, select 'Observation' from the 'Utilities' menu. A pick list with the names of the SPs in the current session will be displayed. This list is only displayed if 'Utilities/Observations' is selected when an exam is not open. See Exhibit 5-2.

Exhibit 5-2. Pick list of SPs in current session



- Select the name of the SP for whom an observation referral should be sent. Click 'OK.'

Exhibit 5-3. Observation referral in CV Fitness



- Type in the message you would like to send to the physician. When you are finished, click 'OK.'

Exhibit 5-4. Observation referral from CV Fitness in physician's referral review box

The screenshot shows a software window titled "Referral Review Stand:806 Session: 808571". It contains a table with columns for "SP", "Pregnancy", "CBC", "BP", "LED", and "Observation". Each column has sub-columns for "Name", "ID", "Age", "Gender", and "Reviewed Status". A patient named "J. Ball" with ID "926247", age "37", and gender "Male" is listed. Below the table is a "Review in Box Details" window showing "SP ID: 926247", "Name: Jake, Ball", "Age: 37", and "Gender: M". Underneath are tabs for "Pregnancy", "CBC", "BP", "LED", and "Observations". The "Observations" tab is active, showing a section titled "OBSERVATIONS Cardiovascular Fitness" with the text: "This is the place to write an observation referral to the MEC physician about this SP. Type your message here. The system will send the message to the physician. The SP will not be checked out of the MEC until the physician has reviewed this message."

- This is the referral as it appears in the physician's referral review box. The message typed in the observation referral box in CV Fitness appears in this box in the physician referral review.
- The physician will review this referral and make a decision about further action if warranted.
- The SP cannot be checked out of the MEC until the physician has reviewed this referral.

5.2 Report of Findings for CV Fitness

Each SP will be given a report of the results or findings for the exams performed. The Report of Findings for the Cardiovascular Fitness Exam will include a report on the SP's level of cardiovascular fitness. The level of cardiovascular fitness will be based on the estimated maximal oxygen consumption achieved by the SP in the treadmill test. SPs will be categorized as having a low, moderate, or a high level of cardiovascular fitness compared to other people of their age and sex.

Reference ranges for estimated maximal oxygen consumption (VO₂ max) are listed in Appendix I. The level of cardiovascular fitness is categorized based on gender-age specific cut-points of

estimated VO2 max. The reference cut-points used for adults 20-49 years are based on data from the Aerobics Center Longitudinal Study (ACLS).^{1,2} Low level of CV fitness is defined as an estimated VO2 max below the 20th percentile of the ACLS data of the same gender and age group; moderate fitness is defined as a value between the 20th and 59th percentile, and high fitness level is defined as at or above the 60th percentile. The reference standards used for adolescents and young adults 12-19 years are based on the criteria used in the FITNESSGRAM program.^{3,4}

General Statement

“Your fitness test was done on a treadmill. The test consisted of a warm-up, two exercise periods (Stage 1 and Stage 2), and a recovery period. The table below shows your test results.

<u>Stage</u>	<u>Required time</u>	<u>Your time</u>	<u>Your heart rate</u>
Warm-up	2 min.		
Stage 1	3 min.		
Stage 2	3 min.		
Recovery	2-3 min.		

During this exercise your maximum incline on the treadmill was ___ percent and your maximum speed was _____ mph.

Compared with other people of your age and sex, your cardiovascular fitness level is *<low, moderate, high>*.”

In addition to the general statement, the report will include the speed and grade of the treadmill at each of the stages in the treadmill test and the length of time spent in each of the stages. SPs will be given this report just before they leave the MEC. The report includes a phone number to call if they have any questions about this or any part of the exam in the MEC.

References

1. American College of Sports Medicine. (1995). *ACSM's Guidelines for Exercise Testing and Prescription*, 6th edition. Philadelphia, PA: Lippincott Williams and Wilkins Company.
2. Blair, S.N., Kohl, H.W. 3rd, Paffenbarger, R.S. Jr., et al. (1989). *Physical Fitness and All-Cause Mortality. A Prospective Study of Healthy Men and Women*. JAMA, 262(17), 2395-401.
3. Cureton, K.J. and Warren, G.L. (1990). *Criterion-Referenced Standards for Youth Health-Related Fitness Tests: A Tutorial*. Research Quarterly for Exercise and Sport, 61(1), 7-19.
4. Cureton, K.J. and Plowman, S.A. (1999). *Aerobic Capacity Assessments*. In Welk G.J., Morrow, J.R. Jr., and Falls H.B. (Ed.) *Fitnessgram Reference Guide* (pp. 66-86). Dallas, TX: Cooper Institute. Available at: <http://dev.cooperinst.org/shopping/PDF%20format/Fitnessgram%20Reference%20Guide.pdf>

6. QUALITY CONTROL

6.1 Overview

Quality assurance/quality control procedures for the Cardiovascular Fitness component includes development of standard procedures for the treadmill test, and intensive training and certification of technologists prior to the start of the study. After study start-up, technologist adherence to procedures is monitored regularly through observational visits and specific data analysis for evaluation of technologist performance. The validity and reliability of specific data is also monitored routinely in addition to regular equipment calibration and maintenance procedures.

6.2 Training

A 5-day training period for the Cardiovascular Fitness component is conducted at the beginning of the study with a 2-day annual retraining. Consultants from the Cooper Institute of Aerobic Research and Westat development staff supervise training for the treadmill test, data entry, and integration issues with the biomedical equipment and the computer system.

6.2.1 Initial Training

The initial training period includes a discussion of the importance of collecting data on the cardiovascular fitness level of the Nation, followed by a brief overview of exercise physiology focusing on normal and abnormal responses to a graded exercise test. Methods for excluding participants from this component (medical history, medications, heart rate and blood pressure criteria, and safety exclusion questions) are reviewed. Technologists are taught how to explain and demonstrate the treadmill test to a participant and how to monitor a participant's comfort level and to observe signs of distress that would require stopping the test early. Operation, maintenance, and calibration procedures for the treadmill, programmable controller, and automatic blood pressure monitor are reviewed and practiced. Procedures for a normal treadmill test are taught in addition to special procedures for changing the exercise protocol, interrupting the test to go to the recovery stage early, or to stop the test immediately if the condition of the

participant warrants it. Data entry and integration of the biomedical equipment is demonstrated and practice sessions are conducted.

A modular approach to training is used where the technologists are given classroom lectures using slide presentations and familiarization with each piece of equipment in a classroom session. The technologist learns how to use the blood pressure monitor and to obtain heart rate and blood pressure readings in one session. Another session is used to familiarize the technologists with the operation of the treadmill and programmable controller. Other classroom sessions are used to train technologists in procedures for asking questions, giving explanations, and reading scripts. Once the technologists are exposed to modular aspects of the treadmill test procedures in the classroom setting, practice sessions are moved to the mobile examination center (MEC). Here the technologists are given an opportunity to complete a practice treadmill on a classmate. This provides an opportunity for the technologist to experience a treadmill test from the participant's perspective and to practice the test in a low stress situation. Volunteer participants are used for the latter part of training to expose technologists to a variety of individuals from diverse backgrounds and age groups, and who are not familiar with the protocol.

At the end of the training session, each technologist is given a written exam and a technologist competency form is completed. The technologists must pass the written exam and complete all the competencies on the form before being cleared to conduct the treadmill test. Technologists who do not pass the exam or have not completed all competencies will be given additional training and testing on aspects of the procedures that need more attention. A debriefing session is held at the end of training and technologists are given individual and group feedback on performance.

6.2.2 Annual Retraining

Annual retraining is conducted over a 2-day period onsite in the MECs. Topics for these sessions includes protocol changes that have been started within the last year, staff requests, and procedures that have caused problems or have been noted on quality control visits. A CIAR consultant and the Westat project staff person conduct these sessions. The retraining is given on both an individual and group level. Each technologist is observed for a minimum of two treadmill tests and is individually questioned on specific protocol issues and is questioned on responses or actions that should be taken to specific scenarios.

A debriefing session is held at the end of the retraining session to provide an opportunity for group discussion and mutual feedback on this component including problem areas, unusual situations, and any modifications in procedures. A Technician Competency Evaluation Form is completed for each technologist and a Site Visit Report form is completed for each team.

Additional training is conducted throughout the year if necessary, depending on protocol changes, technologist performance, and quality control reports.

6.3 Equipment and Room Set-up Checks

The equipment, room supplies, and room set-up need to be checked on a regular basis. Some checks are completed daily and others need only be completed on a weekly basis or at the beginning of each stand. These checks include calibration checks, maintenance inspection of equipment and supplies, and preparation of the room and equipment for the session exams.

Each time you log on to the application, the system will remind you to do Quality Control (QC) checks if the checks have not been completed for that time period. The checks are to be completed daily, weekly, and/or every stand. If you do not have time to do the checks when you log on, you can bypass this message and complete the checks at a later time. However, this message will be displayed each time you log on until you have completed the checks for that time period. Once you have completed the checks and entered this in the system, the message box with the reminder will not be displayed again until the appropriate time period has passed.

The daily, weekly, and once-a-stand checks are listed in the following sections.

6.3.1 Daily

- Confirm that the daily equipment checks are complete.
 - Turn on the power on the treadmill controller.
 - Turn on the power on the blood pressure (BP) monitor. (The Colin STBP-780 is the automated electronic heart rate and blood pressure monitor that will be used

to measure blood pressure and heart rate during the treadmill test. See Chapter 2 for a description and picture of this monitor.)

- Confirm that the BP monitor power cord is plugged in at the power source and on the back of the BP monitor.
- Confirm that the computer cable for the BP monitor is securely connected at the back of the BP monitor.
- Confirm that the BP microphone and airhose are securely connected to the back of the BP monitor.
- Confirm that the cable from the treadmill is securely connected to the back of the treadmill controller.
- Confirm that the treadmill power cord is securely plugged in to the power source.
- Check that the digital thermometer has registered the room temperature.
- Check that the treadmill belt is centered in the roller.
- Visually inspect walking belt for hazards.
- Clean surface of belt with disinfectant wipes.
- Clean both sides of all BP cuffs with disinfectant wipes. (Cuffs are also wiped after each exam.)
- Visually inspect BP cuffs and hoses for cracks and tears.
- Check that each BP cuff is hanging properly from the clip on the grid. The microphone wires (taped areas on air hose below cuff) should be hanging free - not twisted or bent.
- Check that all shoes are in the shoe rack.
- Confirm that supplies (electrodes, alcohol, and abrasive pads) are stocked for today's session.

6.3.2 Weekly

- Complete all daily checks.
- Check speed of treadmill. See Section 2.1.2.1.
- Check grade of treadmill. See Section 2.1.2.2.

- Check belt tension on treadmill. See Section 2.1.1.1.
- Check belt tracking on treadmill. See Section 2.1.1.2
- Check rear roller guards on treadmill. See Section 2.1.1.3
- Check calibration on BP monitor with mercury manometer (0-70 mmHg within +/- 5 mmHg). See Section 2.3.2.
- Check calibration on BP monitor with mercury manometer (70-120 mmHg within +/- 5 mmHg).
- Check calibration on BP monitor with mercury manometer (120-180 mmHg within +/- 5 mmHg).
- Check calibration on BP monitor with mercury manometer (180-220 mmHg within +/- 5 mmHg).
- Check calibration on BP monitor with mercury manometer (220-255 mmHg within +/- 5 mmHg).
- Check that calibration mercury manometer is intact. See Section 2.3.3.
- Calibrate the SECA scale - weekly weight check. If the scale is off, do a full calibration and if the scale is off by a pound or more with the 5 weights on it, inform the MEC manager and a replacement scale will be sent to the MEC. See Section 2.4.1 for calibration procedures.
- Calibrate the SECA stadiometer. If the reading is off by greater than 1 cm, inform the MEC manager. Use the stadiometer until a replacement is sent. See Section 2.4.2 for calibration procedures.

6.3.3 Stand

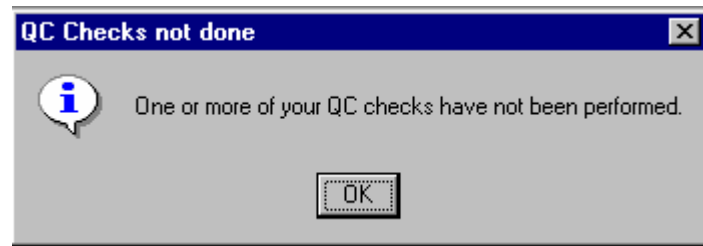
- Complete all daily checks.
- Complete all weekly checks.
- Remove all BP cuffs from bladder and wash cuffs with soap and water. Allow drying.
- Wipe down BP monitor with cloth dampened with water. Do not use alcohol.
- Wipe down treadmill controller with cloth dampened with water. Do not use alcohol.
- Confirm treadmill controller settings for speed and grade for all stages are accurate (for each of the eight protocols) (Chief technologist).

- Confirm with the data manager that the BP monitor is plugged in to an uninterruptible power supply (UPS). (Enter 'Confirmed' with {initials of data manager} in Comments field).
- Confirm with the data manager that the treadmill and the UPS for the BP monitor are on different power circuits. (Enter 'Confirmed' with {initials of data manager} in Comments field).
- Calibrate SECA scale - Full. If the scale is off by 1 pound or more with the 5 weights placed on it, inform the MEC manager. A replacement scale will be sent to the MEC. See Section 2.4.1 for calibration procedures.
- Calibrate SECA stadiometer. If the reading is off by greater than 1 cm, inform the MEC manager. Use the stadiometer until a replacement is sent. See Section 2.4.2 for calibration procedures.

6.4 Data Entry Screens for QC on Equipment

6.4.1 Quality Control Reminder Message Box

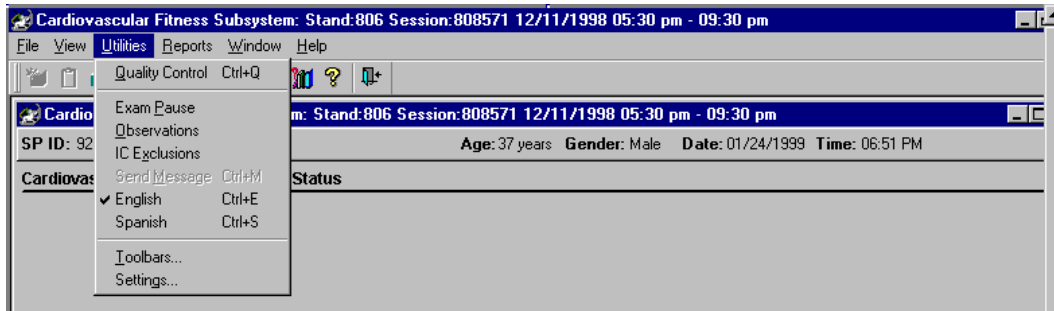
Exhibit 6-1. Quality control reminder message box



- When you log on to the application before the quality control checks are performed, the system displays a message: 'One or more of your QC checks have not been performed.' See Exhibit 6-1.
- Click 'OK' to this message.

6.4.2 Utilities Menu to Select Quality Control

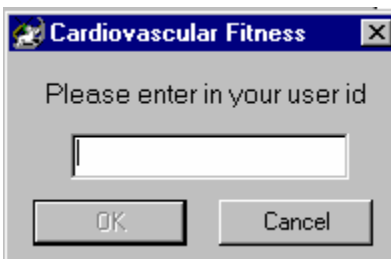
Exhibit 6-2. Utilities menu to select quality control



- When you want to complete the QC checks, select 'Utilities.' Then select 'Quality Control' from the menu. See Exhibit 6-2.
- Clicking on the QC icon from the Toolbar can also access the QC screens.

6.4.3 Quality Control Logon Box

Exhibit 6-3. Quality control logon



When QC is selected from the Utilities menu, the User ID entry box will be displayed. See Exhibit 6-3. Each technologist will have a personal ID. This ID will be used to identify the person who completed the QC checks for this time period.

- Enter your User ID and click 'OK.'
- If you do not want to do the QC checks at this time, click 'Cancel.'

6.4.4 Data Entry Screen for QC Daily Checks

Exhibit 6-4. Quality control daily checks (1)

QC Check	Done	Result	Comment
Turn power on treadmill controller.	<input type="checkbox"/>		
Turn power on BP monitor.	<input type="checkbox"/>		
Confirm BP monitor power cord is plugged in at UPS and at back of BP monitor.	<input type="checkbox"/>		
Confirm computer cable for BP monitor is securely connected at back of BP monitor.	<input type="checkbox"/>		

On the QC screens, check 'Done' for the listed items when that item has been completed. You are not required to enter anything in the 'Result' or 'Comment' fields unless there is a problem. The 'Result' field is used to enter values for selected QC items if required. The 'Comment' field is used to enter information about problems encountered with the QC item check. This field is also used to indicate if something has been reported or confirmed with another staff member (Chief technologist, MEC manager, data manager).

- Turn on the power to the treadmill controller and the BP monitor.
- Confirm that the power cord on the BP monitor is plugged in securely at the back of the monitor and at the UPS.
- Confirm that the computer cable connecting the BP blood pressure monitor to the ISIS monitor is connected securely to the back of the blood pressure monitor.

Exhibit 6-5. Quality control daily checks (2)

QC Check	Done	Result	Comment
Confirm BP microphone and airhose are securely connected at back of BP monitor.	<input type="checkbox"/>		
Confirm cable from treadmill is securely connected to back of treadmill controller.	<input type="checkbox"/>		
Confirm treadmill power cord is securely plugged in to power source.	<input type="checkbox"/>		
Check digital thermometer has registered room temperature.	<input type="checkbox"/>		

Use the scroll bar to move to the next items on the list. See Exhibit 6-5.

- Confirm that the microphone and air hose are securely connected at the back of the BP monitor.
- Confirm that the cable from the treadmill is securely connected to the back of the treadmill controller.
- Confirm that the treadmill power cord is securely plugged into the power source.
- Check that the digital thermometer has registered the room temperature.

Exhibit 6-6. Quality control daily checks (3)

QC Check	Done	Result	Comment
Check treadmill belt is centered in roller.	<input type="checkbox"/>		
Visually inspect walking belt for hazards.	<input type="checkbox"/>		
Clean surface of belt with disinfectant wipes.	<input type="checkbox"/>		
Clean both sides of all BP cuffs with disinfectant wipes. (Cuffs are also wiped after each exam.)	<input type="checkbox"/>		

See Exhibit 6-6 for the additional items.

- Check that the treadmill belt is centered in the rollers.
- Visually inspect the walking belt for objects that may have been left on the belt. Remove all objects and keep the belt clear for the entire session.
- Wipe down the belt with disinfectant wipes.
- Clean both sides of the BP cuffs with disinfectant wipes. The BP cuffs should be wiped down with disinfectant wipes after each use.

Exhibit 6-7. Quality control daily checks (4)

QC Check	Done	Result	Comment
Visually inspect BP cuffs and hoses for cracks and tears.	<input type="checkbox"/>		
Check BP cuffs are hanging from clip on grid with no twisting on microphone wires.	<input type="checkbox"/>		
Check that all shoes are in the shoe rack.	<input type="checkbox"/>		
Confirm electrodes, alcohol and abrasive pads are stocked for this session.	<input type="checkbox"/>		

- See Exhibit 6-7 for the remaining items.
- Check all BP cuffs and hoses for cracks and tears.
- Check that the cuffs are hanging properly from the grid. The cuffs should be clipped to the grid with the weight of the microphone tubing and air hose supported in the basket beneath. There should be no twisting on the microphone wires.
- Check that all shoes are in the shoe rack.
- Confirm that there are adequate supplies for the entire session and restock as necessary.
- When you are finished with the daily item checks, click 'OK' to close the QC box.

6.4.5 Data Entry Screen for QC Weekly Checks

Exhibit 6-8. Quality control weekly checks (1)

QC Check	Done	Result	Comment
Complete all daily checks.	<input type="checkbox"/>		
Check speed of treadmill.	<input checked="" type="checkbox"/>	Difference=0.8	Controller speed=2.5,Belt speed=3.3; Reported to MEC Manager
Check grade of treadmill.	<input type="checkbox"/>		
Check belt tracking on treadmill.	<input type="checkbox"/>		

- Complete all daily checks. Check 'Done' for each item on the weekly checks when complete. See Exhibit 6-8.
- Check speed of the treadmill. See Section 2.1.2.1 for calibration procedures for speed of treadmill. If the speed readout on the treadmill controller exceeds +/- 0.2 mph of actual speed, repeat the procedure. If the treadmill still exceeds the range, enter the difference between the belt speed on the controller and the calculated belt speed in the 'Result' field. (Example: Difference = 0.8 mph). Enter the speed of the treadmill controller and the calculated belt speed in the 'Comment' field. (Example: Controller speed = 2.5 mph; Belt speed = 3.3 mph). Report this to the chief technologist. Note this report in the 'Comment' field. (Example: Reported to chief technologist). The chief technologist or MEC manager will call a service representative.
- Check grade of the treadmill. See Section 2.1.2.2 for calibration procedures for grade of treadmill. If the elevation error exceeds +/- 1% grade, repeat the calibration check. If the elevation error still exceeds +/- 1% grade, enter the elevation error in the 'Result' field. (Example: Elevation error = 1.5%). Enter the treadmill grade setting and the measured grade in the 'Comment' section. (Example: Treadmill grade setting=20%; Measured grade=21.5%). Report this to the chief technologist. Note the report in the 'Comment' section. (Example: Reported to chief technologist.). The chief technologist will call a service representative.
- Check belt tracking on treadmill. See Section 2.1.1.2.

Exhibit 6-9. Quality control weekly checks (2)

QC Check	Done	Result	Comment
Check belt tension on treadmill.	<input type="checkbox"/>		
Check rear roller guards on treadmill.	<input type="checkbox"/>		
Check calibration on STBP monitor with mercury manometer (0-70 mmHg within +/- 5 mmHg).	<input type="checkbox"/>		
Check calibration on STBP monitor with mercury manometer (70-120 mmHg within +/- 5 mmHg).	<input type="checkbox"/>		

- Check belt tension on treadmill. See Section 2.1.1.1 for a description of how to check treadmill belt tension.
- Check rear roller guards. See Section 2.1.1.3 for a description of how to check rear roller guards.
- Check calibration on the BP monitor with the mercury manometer (0-70 mmHg within +/- 5 mmHg). See Section 2.3.2 for BP calibration procedures. If the BP calibration checks are not within the acceptable range, enter the difference between the mercury manometer reading and the reading on the BP monitor in the 'Result' field. (Example: Difference = 8mmHg). See Figure 6-10. Enter the reading on the manometer and the reading on the BP monitor in the 'Comment' field. (Example: Manometer = 110; BP=118). Notify the chief technologist. Make a note of this in the 'Comment' section. (Example: Reported to the chief technologist.)
- Check calibration on BP monitor with mercury manometer (70-120 mmHg within +/- 5 mmHg). If the BP calibration checks are not within the acceptable range, follow the same procedures as in the preceding bullet.

Exhibit 6-10. Quality control weekly checks (3)

QC Check	Done	Result	Comment
Check calibration on STBP monitor with mercury manometer (120-180 mmHg within +/- 5 mmHg).	<input checked="" type="checkbox"/>	Difference=8	Manometer=110; STBP=118. Reported to MEC Manager.
Check calibration on STBP monitor with mercury manometer (180-220 mmHg within +/- 5 mmHg).	<input checked="" type="checkbox"/>	Difference=8	Manometer=110; STBP=118. Reported to MEC Manager.
Check calibration on STBP monitor with mercury manometer (220-255 mmHg within +/- 5 mmHg).	<input checked="" type="checkbox"/>	Difference=8	Manometer=110; STBP=118. Reported to MEC Manager.
Check calibration mercury manometer is intact.	<input checked="" type="checkbox"/>		

- Check calibration on the BP monitor with the mercury manometer (120-180 mmHg within +/- 5 mmHg). If the BP calibration checks are not within the acceptable range, follow the same procedures as in the first bullet for calibration of the BP monitor.
- Check calibration on the BP monitor with mercury manometer (180-220 mmHg within +/- 5 mmHg). If the BP calibration checks are not within the acceptable range follow the same procedures as in the first bullet for calibration of the BP monitor.
- Check calibration on the BP monitor with mercury manometer (220-255 mmHg within +/- 5 mmHg). If the BP calibration checks are not within the acceptable range, follow the same procedures as in the first bullet for calibration of the BP monitor.
- Check that the calibration of the mercury manometer is intact. The procedures for this are in Section 2.3.3 and are also on the laminated Quick Reference cards in the CV Fitness room.

Exhibit 6-11. Quality control weekly checks (4)

QC Check	Done	Result	Comment
Check calibration on STBP monitor with mercury manometer (220-255 mmHg within +/- 5 mmHg).	<input type="checkbox"/>		
Check calibration mercury manometer is intact.	<input type="checkbox"/>		
Calibrate SECA Scale - weekly weight check	<input type="checkbox"/>		
Calibrate SECA stadiometer	<input type="checkbox"/>		

- Calibrate the SECA scale - weekly weight check. If the scale is off, do a full calibration and if the scale is off by a pound or more with the 5 weights on it, inform the MEC manager and a replacement scale will be sent to the MEC. See Section 2.4.1 for calibration procedures.
- Calibrate the SECA stadiometer. If the reading is off by greater than 1 cm, inform the MEC manager. Use the stadiometer until a replacement is sent. See Section 2.4.2 for calibration procedures.

6.4.6 Data Entry Screen for QC Start of Stand Checks

Exhibit 6-12. Quality control 'start of stand' checks (1)

QC Check	Done	Result	Comment
Complete all daily checks.	<input type="checkbox"/>		
Complete all weekly checks.	<input type="checkbox"/>		
Remove all BP cuffs from bladder and wash cuffs with soap and water.	<input type="checkbox"/>		
Wipe down STBP monitor with cloth dampened with water. Do not use alcohol.	<input type="checkbox"/>		

- Complete all daily checks.
- Complete all weekly checks.
- Remove all BP cuffs from bladder and wash cuffs with soap and water. Allow time to dry before using again.
- Wipe down the BP monitor with a damp cloth. Do not use alcohol.

Exhibit 6-13. Quality Control 'start of stand' checks (2)

QC Check	Done	Result	Comment
Wipe down treadmill controller with cloth dampened with water. Do not use alcohol.	<input type="checkbox"/>		
Confirm treadmill controller settings for speed and grade for all protocols.	<input type="checkbox"/>		
Confirm with Data Manager that BP monitor is plugged in to UPS. (Enter 'Confirmed with DM' in Comments field)	<input type="checkbox"/>		
Confirm with DM that UPS for BP monitor and treadmill are on different power circuits. (Enter 'Confirmed with DM')	<input type="checkbox"/>		

- Wipe down treadmill controller with cloth dampened with water. Do not use alcohol.

- Confirm treadmill controller settings for speed and grade for all protocols. The chief technologist is responsible for doing this check. See Section 2.2.3 for details and Appendix J for the Speed and Grade Table by Protocol and Stage. These procedures and the table are also on the laminated Quick Reference cards in the CV Fitness room.
- Confirm with the data manager that the BP monitor is plugged into the UPS. Enter 'Confirmed with the data manager' in the Comment field.
- Confirm with the data manager that the UPS for BP monitor and treadmill are on different power circuits. Enter 'Confirmed with the data manager' in the Comment field. If not, ask him/her to do this and then enter 'Confirmed with the data manager' in the Comment field. The BP monitor should be plugged into the UPS in the room to minimize the 'noise' to the monitor from the treadmill and other sources.

Exhibit 6-14. Quality Control 'start of stand' checks (3)

QC Check	Done	Result	Comment
Confirm with Data Manager that BP monitor is plugged in to UPS. (Enter 'Confirmed with DM' in Comments field)	<input type="checkbox"/>		
Confirm with DM that UPS for BP monitor and treadmill are on different power circuits. (Enter 'Confirmed with DM')	<input type="checkbox"/>		
Calibrate SECA Scale - Full	<input type="checkbox"/>		
Calibrate SECA stadiometer	<input type="checkbox"/>		

- Calibrate SECA scale - Full. If the scale is off by 1 pound or more with the 5 weights placed on it, inform the MEC manager. A replacement scale will be sent to the MEC. See Section 2.4.1 for calibration procedures.
- Calibrate SECA stadiometer. If the reading is off by greater than 1 cm, inform the MEC manager. Use the stadiometer until a replacement is sent. See Section 2.4.2 for calibration procedures.
- When the 'Start of Stand' checks are complete, click 'OK' to close the QC checks.

6.4.7 Incomplete Entry of Quality Control Data

Exhibit 6-15. Quality control incomplete entry

The screenshot shows a window titled "Cardiovascular Fitness Quality Control Checks" with tabs for "Start of Stand", "Daily", and "Weekly". The "Daily" tab is selected. Below the tabs is a table with columns "QC Check", "Done", "Result", and "Comment".

QC Check	Done	Result	Comment
Remove all BP cuffs from bladder and wash cuffs with soap and water.	<input checked="" type="checkbox"/>		
Wipe down STBP monitor with cloth dampened with water. Do not use alcohol.	<input checked="" type="checkbox"/>		
Wipe down treadmill controller with cloth dampened with water. Do not use alcohol.	<input checked="" type="checkbox"/>		
Confirm treadmill controller settings for speed and grade for all protocols.	<input type="checkbox"/>		

Below the table, a blue error message box is displayed with a yellow warning icon and the text: "Not all of the QC items were done. Do you wish to exit?". At the bottom of the error box are "Yes" and "No" buttons. The main dialog box has "OK" and "Cancel" buttons at the bottom right.

- When you have completed all checks, click 'OK' to close the QC box.
- If you do not check that all items are complete, the system will display this message: 'Not all the QC items were done. Do you wish to exit?' See Exhibit 6-15.
- If you want to complete the items before exiting, click 'No' to this message and complete the items.
- If you do not wish to exit without completing all the QC checks, click 'Yes' to this message.
- If all QC items were not complete, the system will remind you each time you log on that the QC checks are not complete.

6.5 Observational Visits

The Cardiovascular Fitness component has two types of quality control visits, expert visits conducted by consultants from the Cooper Institute of Aerobic Research (CIAR) and nonexpert visits conducted by Westat project development staff. Consultants from the CIAR will make two field visits per team per year. Each visit will last approximately 2 days. Whenever possible, visits will be made during

peak testing days in order to observe as many CV tests as possible. The consultants will complete the Technician Competency Evaluation form (See Section 6.5.1) during each test and review the completed form with the technologist. Any necessary improvements that need to be made by the technologist will be documented on the form, and the technologist will sign the form after reading it. Technologists who are observed having CV testing problems during field visits will be observed more frequently than other technologists. A secondary activity during each site visit will be to monitor the physician's examination to ensure that the CV exclusion questions are being asked according to the script.

Nonexpert quality control visits are conducted twice a year for each team. Westat development staff for this component will conduct these visits to monitor procedures and to conduct re-training for changes in procedures if necessary. A Site Visit Report form is completed by the consultants and development staff following each field visit. The Site Visit Report form is used to identify, document, and follow up on issues or problems noted during observational field visits. In contrast to the Technician Competency Evaluation form, the Site Visit Report form is used to give an overall assessment of the status of the component and team performance. The intent is to report general problems and issues rather than problems and issues regarding the specific performance of specific technologists. The latter is reported on the Technician Competency Evaluation form.

6.5.1 Technician Competency Evaluation Form

This form is used by consultants and trainers to evaluate health technologists conducting the exam. Items are checked as Pass/Fail. If the technologist does not pass an item, the observer will discuss this with the technologist, offer suggestions for improvement, and re-evaluate performance in a subsequent exam later in that visit or at the next visit. See template form in Exhibit 6-16.

Exhibit 6-16. Technician Competency Evaluation Form

**NHANES CARDIOVASCULAR FITNESS COMPONENT
Quality Control
Technician Competency Evaluation Form**

Technician Name: _____ Stand Number: _____

Cooper Institute Examiner Name: _____ Date: _____

	Satisfactory	Unsatisfactory
Introduction to Component		
<ul style="list-style-type: none"> ■ Greets SP and brings into treadmill room ■ Provides brief overview of treadmill component ■ Scans SP identification number into system 		
Obtaining Weight and Height Measurement		
<ul style="list-style-type: none"> ■ Position SP on the weight scale and instruct SP to stand still prior to taking weight measurement ■ Position SP on the stadiometer and instruct SP to inhale prior to taking height measurement ■ Enters answers correctly into system 		
Determination of PAR Code		
<ul style="list-style-type: none"> ■ Reads questions clearly and quickly ■ Encourages SP to answer questions quickly ■ Enters answers correctly into system 		
Check Appropriate Footwear		
<ul style="list-style-type: none"> ■ No heels, cleats, or dress shoes ■ Shoes tied securely 		
Preparation of Skin and Placement of Electrodes		
<ul style="list-style-type: none"> ■ Correctly identifies electrode sites ■ Thoroughly wipes each site with alcohol swab ■ Lightly abrades skin at each site (6-10 swipes) ■ Applies electrode at each site and presses firmly ■ Clips RA, LA, RL, and LL wires to appropriate electrodes 		
Blood Pressure Cuff Placement		
<ul style="list-style-type: none"> ■ Selects appropriately sized cuff ■ Palpates for brachial artery ■ Places cuff 1 inch (2-3 cm) above antecubital space ■ Places cuff so that 2 microphones are directly over brachial artery ■ Cuff placed snugly, no slipping 		

Exhibit 6-16. Technician Competency Evaluation Form (continued)

	Satisfactory	Unsatisfactory
■ Explanation of Treadmill Test		
■ Follows script, speaks clearly		
Obtaining Pretest Blood Pressure and Heart Rate		
■ Instructs SP to stand quietly on treadmill with arms by sides		
■ Selects arm and cuff size on ISIS screen		
■ Selects Capture on ISIS screen		
Selecting Protocol On Treadmill Controller		
■ Presses ENTER, then INPUT + twice on controller		
■ Presses INPUT + or INPUT – until the correct protocol number is displayed on the controller		
Tech Demonstrates How to Walk on Treadmill		
■ Straddles belt near front, holding onto front rail		
■ Presses START BELT on treadmill controller		
■ Begins walking, stands up straight, takes long steps, looks ahead, drops right hand first, then left hand		
■ Presses STOP BELT on treadmill controller		
■ Presses CLEAR on treadmill controller		
Getting SP on to the Treadmill		
■ Instructs SP to straddle belt near front, holding onto front rail		
■ Presses START BELT on treadmill controller		
■ Instructs SP to step on belt and begin walking (big steps, eyes ahead, stand up straight)		
Starting the Treadmill Test		
■ Presses START on ISIS screen and press START COURSE on treadmill controller at the same time		
■ Encourages SP to let go of front rail one hand at a time		
■ A light touch with fingertips is OK, but no gripping rail		
■ If SP continues to grip front rail by end of warm-up, press GO TO RECOVERY on ISIS screen, press NEXT STAGE on treadmill controller so that recovery stage is displayed		
Explanation of RPE		
■ Reads script quickly and clearly when prompted by ISIS		
Obtaining RPE – Warm Up		
■ Asks SP for RPE at 1:30 of warm-up following auditory prompt from ISIS		
■ Enters RPE correctly into system		

Exhibit 6-16. Technician Competency Evaluation Form (continued)

	Satisfactory	Unsatisfactory
Normal Transition From Warm-Up to Stage I		
<ul style="list-style-type: none"> ■ Presses NEXT STAGE on treadmill controller at 1:59 following auditory prompt from ISIS 		
Obtaining RPE – Stage I		
<ul style="list-style-type: none"> ■ Asks SP for RPE at 2:30 of Stage I following auditory prompt from ISIS ■ Enters RPE correctly into system 		
Check HR – Stage I		
<ul style="list-style-type: none"> ■ Check heart rate on BP monitor and captured data in ISIS ■ Manually enter correct HR into system if the difference is > 5 beats ■ HR checked _____ HR captured _____ HR entered _____ 		
Obtaining RPE – Stage II		
<ul style="list-style-type: none"> ■ Asks SP for RPE at 2:30 of Stage II following auditory prompt ■ Enters RPE correctly into system 		
Check HR – Stage II		
<ul style="list-style-type: none"> ■ Check heart rate on BP monitor and captured data in ISIS ■ Manually enter correct HR into system if the difference is > 5 beats ■ HR checked _____ HR captured _____ HR entered _____ 		
Normal Recovery		
<ul style="list-style-type: none"> ■ Informs SP that treadmill will be slowing down and grade will level out ■ Informs SP that it is OK to lightly touch front railing on treadmill during recovery 		
Normal Test Termination		
<ul style="list-style-type: none"> ■ Presses COOL DOWN on treadmill controller after auditory prompt from ISIS ■ Tells SP to grab front rail because treadmill is about to stop ■ Presses STOP BELT on treadmill, be attentive to SP ■ Detaches lead wires from electrodes ■ Selects FINISH on ISIS screen 		
Changing Protocols (example scenario for decreasing protocol)		
<ul style="list-style-type: none"> ■ At 1:30 of warm-up, examiner presents scenario that warm up heart rate is >60% of predicted max ■ Selects CHANGE PROTOCOL on ISIS screen ■ Selects DECREASE and APPLY on ISIS screen ■ At 1:59 presses NEXT STAGE 4 times on treadmill controller so that next easiest protocol (Stage I) is selected 		

6.5.2 Quality Control Review of CV Fitness exclusions in Physician's Exam

Two activities in the physician's exam are related to the cardiovascular fitness component: reviewing medications recorded at the SP household questionnaire for safety exclusions and administering CV fitness exclusion questions.

Medication Review

Physicians are responsible for reviewing the medications reported by the SP at the household interview. Physicians will then determine if the SP should be excluded from the CV fitness exam based on a list of exclusion medications that are updated quarterly by the consultants from the Cooper Institute. This review process is expected to take place at the beginning of the session. The following form (Exhibit 6-17) lists the observation points for this part of the activity.

Exhibit 6-17. Checklist for medication review

Observation points	Yes	No	Specific comments and notes
Reported medications are reviewed with the exclusion list			
Result of the review is recorded correctly			

CV Fitness Exclusion Questions

A set of exclusion questions will be asked in the Physician Exam for the CV fitness component. This is a second level of safety check to prevent including SPs who may have been recently diagnosed with one of the exclusion medical conditions or have started taking one of the exclusion medications in the time period since the household interview. If the SP responds affirmatively to any of the exclusion questions, he or she will be immediately excluded and will not need to answer the remaining questions. Physicians are expected to read these questions exactly as written. Below is a checklist (Exhibit 6-18) used by the trainers in the field. The purposes of this list are to monitor the administration of the CV fitness exclusion questions and to aggregate specific comments for these questions, especially the necessity and appropriateness for extra prompt use.

Exhibit 6-18. Checklist for CV Fitness exclusion questions

CV Fitness exclusion questions	Follow script		SP receptive		Prompt use		Specific comments and notes
	Yes	No	Yes	No	Yes	No	
Have you been hospitalized in the past 3 months?							
Has a doctor ever said you should not participate in sports or other activities because of a health condition? (12-19 years only)							
Has a doctor ever said you have a heart condition and that you should only do physical activity recommended by a doctor?							
Do you feel pain in your chest when you do physical activity? (20-49 years only)							
In the past month, have you had chest pain when you were not doing physical activity? (20-49 years only) <i>Probe: Have you seen a medical doctor about your chest pain? Did the doctor tell you that the chest pain was related to your heart?</i>							
Do you lose your balance because of dizziness? <i>Probe: Is this an isolated incident or does it occur on a regular basis?</i>							
Do you ever lose consciousness? <i>Probes: Did this occur as a result of illness or was it unexplained? Is this an isolated incident or does it occur on a regular basis?</i>							
Do you have a bone or joint problem that could be made worse by walking? <i>Probe: Do you think you can do the test without injuring yourself?</i>							
Are you currently taking any prescription medications?							
Are you currently taking any prescription medications for your blood pressure?							
What is the name of this medication?							
Are you currently taking prescription medications for the following conditions: heart condition, or prescription eye drops for glaucoma?							
Do you know of any other reason why you should not do a treadmill test?							

6.5.3 Site Visit Report Form

The Site Visit Report form (Exhibit 6-19) is an online method to identify, document, and followup on issues or problems noted during observational field visits. This form is completed by consultants and development staff following each field visit and is posted to the project intranet site.

In contrast to the Technician Competency Evaluation form, the Site Visit Report form is used to give an overall assessment of the status of the component and team performance. The intent is to report general problems and issues rather than problems and issues regarding the specific performance of specific technologists. The latter is reported on the Technician Competency Evaluation form.

Exhibit 6-19. Site Visit Report form

Date(s) of Visit:		Stand #	
Name of Observer:		Visit # (this year to this team)	
Component:	Cardiovascular Fitness	# of SP exams observed:	
ID number of examiners/recorders observed			
<ol style="list-style-type: none"> 1. Outstanding issues from last visit or QC meeting (if any): 2. Observations/issues: 3. Issues that need to be addressed at the next visit: 4. Comments: 			

APPENDIX A
SCRIPTS

APPENDIX A

SCRIPTS

Introduction to Component (Suggested Script)	
English	Spanish
In this exam we want to get some information about your cardiovascular fitness or the fitness of your heart. We will be asking you to walk on the treadmill while we monitor your heart rate and blood pressure. I will explain this in more detail in a few minutes but first I want to ask you a few questions about your health in general. Please come over here near the computer while I scan your identification number into the system.	En este examen queremos obtener alguna información acerca de su condición cardiovascular o la condición del corazón. Le pediremos que camine sobre la máquina de andar mientras le monitoreamos la frecuencia cardíaca (los latidos del corazón) y la presión de sangre. Explicaré esto con más detalle en unos pocos minutos pero primero quiero hacerle algunas preguntas acerca de su salud en general. Por favor venga aquí cerca de la computadora mientras anoto con el escáner su número de identificación en el sistema.
Explanation of the Exam (Standard Script)	
English	Spanish
The purpose of the treadmill test is to estimate your cardiovascular fitness level. You will be walking on the treadmill at various speeds and grades. This is not a maximal test to exhaustion. We will stop when your heart rate reaches a certain level. While this is a very safe test, it is important that you let us know how you feel during the test. Please report any unusual symptoms that you have during the test such as chest pain, dizziness, nausea, or pain in your legs.	El propósito de la prueba en la máquina de andar es calcular su nivel de capacidad cardiovascular. Usted caminará en la máquina a diferentes velocidades y grados. Esta no es una prueba máxima de esfuerzo. Pararemos cuando la frecuencia cardíaca (los latidos del corazón) alcance cierto nivel. Si bien esta es una prueba muy segura, es importante que nos diga cómo se siente durante la prueba. Por favor informe cualquier síntoma inusual que tenga durante la prueba tal como dolor en el pecho, mareo, náusea, o dolor en las piernas.
Explanation of Rating of Perceived Exertion (RPE)	
English	Spanish
Please look at the chart on the wall in front of you. Every couple of minutes during the test, I will ask you to rate how hard you feel you are working overall. Please respond with a number from the scale. For example, if you feel that you are working at a very low level of effort, you might reply with a 6 or 7 (very, very light). On the other hand, if you feel you are working at a very high level of effort and cannot continue, you might reply with a 20 (maximal exertion). There is no right or wrong answer, simply rate you level of effort at the time I ask the question.	Por favor mire el gráfico en el muro frente a usted. Cada dos minutos durante la prueba, le pediré que califique qué tan fuerte siente que está trabajando en general. Por favor conteste con un número de la escala. Por ejemplo, si usted siente que está trabajando a un nivel de esfuerzo muy bajo, usted puede responder un 6 ó 7 (muy, muy liviano). Por otra parte, si usted siente que está trabajando a un nivel de esfuerzo muy alto y no puede continuar, usted puede contestar con un 20 (máximo esfuerzo). No hay respuesta correcta o errónea, simplemente califique su nivel de esfuerzo en el momento en que yo le haga la pregunta.

APPENDIX B
EXCLUSIONS BASED ON MEDICAL CONDITIONS

APPENDIX B

SHARED/SAFETY EXCLUSION QUESTIONS

Shared Exclusion Questions	
English	Spanish
Do you have any amputations of your legs and feet other than toes?	¿Tiene alguna amputación de las piernas y pies que no sean los dedos de los pies?
Where is the amputation?	¿Se refiere a la cadera derecha, izquierda o las dos caderas?
How much do you weigh without clothes or shoes?	¿Cuánto pesa sin ropa o zapatos?
Do you have a pacemaker or automatic defibrillator?	¿Tiene un marcapaso o desfibrilador automático?
Are you currently pregnant?	¿Está usted actualmente embarazada?
How many weeks?	¿Cuántas semanas?
Safety Exclusion Questions (Asked in Household Interview, if Yes, then confirmed by Physician)	
English	Spanish
CVQ030. Has a doctor ever said you have a heart condition and that you should only do physical activity recommended by a doctor?	
CVQ040. Do you feel pain in your chest when you do physical activity?	
CVQ050. In the past month, have you had chest pain when you were not doing any physical activity?	
CVQ060. Do you lose your balance because of dizziness?	
CVQ070. Do you ever lose consciousness?	
CVQ080. Do you have a bone or joint problem that could be made worse by walking?	
CVQ165. Do you know of any other reason why you should not walk on a treadmill?	
BeAll Question (asked in Physician's Exam or CV Fitness)	
English	Spanish
Since you were interviewed in your home on {Household Interview Date} have there been any changes in your health or medications that would prevent you from walking on a treadmill for the fitness test?	

APPENDIX C
EXCLUSIONS BASED ON MEDICATIONS

APPENDIX C. EXCLUSIONS BASED ON MEDICATIONS

SP medications are reviewed by the Physician and the SP is excluded from CV Fitness if he or she is taking any of the following medications. Medications are reviewed quarterly and updated if necessary.

Last updated 01-01-2005

Class Code	Class Name	Generic	Drug Name
	CARDIOTONICS/*Cardiac Glycosides**		
312000		Digoxin	DIGITEK
312000		Digoxin	DIGOXIN
312000		Digoxin	DIGOXIN PEDIATRIC
312000		Digoxin	DIGOXIN-TAB
312000		Digoxin	LANOXICAPS
312000		Digoxin	LANOXIN
312000		Digoxin	THSC DIGOXIN
	ANTIANGINAL AGENTS/*Nitrates**		
321000		Amyl Nitrite Inhal	AMYL NITRITE
321000		Amyl Nitrite Inhal	AMYL NITRITE INHAL
321000		Nitroglycerin TD Patch HR HR	DEPONIT
321000		Isosorbide Dinitrate CR	DILATRATE SR
321000		Isosorbide Mononitrate SR HR	IMDUR
321000		Isosorbide Mononitrate	ISMO
321000		Isosorbide Dinitrate CR	ISOCHRON
321000		Isosorbide Dinitrate SL	ISORDIL
321000		Isosorbide Dinitrate	ISORDIL TITRADOSE
321000		Isosorbide Dinitrate	ISOSORBIDE DINITRATE
321000		Isosorbide Dinitrate CR	ISOSORBIDE DINITRATE CR
321000		Isosorbide Dinitrate CR	ISOSORBIDE DINITRATE ER
321000		Isosorbide Dinitrate CR	ISOSORBIDE DINITRATE SA
321000		Isosorbide Dinitrate SL	ISOSORBIDE DINITRATE SL
321000		Isosorbide Dinitrate CR	ISOSORBIDE DINITRATE SR
321000		Isosorbide Dinitrate CR	ISOSORBIDE DINITRATE TD
321000		Isosorbide Dinitrate CR	ISOSORBIDE DINITRATE TR
321000		Isosorbide Mononitrate	ISOSORBIDE MONONITRATE
321000		Isosorbide Mononitrate SR HR	ISOSORBIDE MONONITRATE ER
321000		Isosorbide Mononitrate SR HR	ISOSORBIDE MONONITRATE SR 24HR
321000		Nitroglycerin TD Patch HR HR	MINITRAN
321000		Isosorbide Mononitrate	MONOKET

APPENDIX C. EXCLUSIONS BASED ON MEDICATIONS (continued)

Class Code	Class Name	Generic	Drug Name
	ANTIANGINAL AGENTS/*Nitrates**		
321000		Nitroglycerin TD Patch HR HR	NITREK
321000		Nitroglycerin	NITRO-BID
321000		Nitroglycerin TD Patch HR HR	NITRO-DUR
321000		Nitroglycerin CR	NITRO-TIME
321000		Nitroglycerin	NITROBID
321000		Nitroglycerin CR	NITROCOT SA
321000		Nitroglycerin Buccal CR	NITROGARD
321000		Nitroglycerin	NITROGLYCERIN
321000		Nitroglycerin Buccal CR	NITROGLYCERIN BUCCAL CR
321000		Nitroglycerin CR	NITROGLYCERIN CR
321000		Nitroglycerin CR	NITROGLYCERIN ER
321000		Nitroglycerin IV in D W	NITROGLYCERIN IN
321000		Nitroglycerin IV in D W	NITROGLYCERIN IN DEXTROSE
321000		Nitroglycerin IV in D W	NITROGLYCERIN IV
321000		Nitroglycerin CR	NITROGLYCERIN SA
321000		Nitroglycerin SL	NITROGLYCERIN SL
321000		Nitroglycerin CR	NITROGLYCERIN SR
321000		Nitroglycerin CR	NITROGLYCERIN TD
321000		Nitroglycerin TD Patch HR HR	NITROGLYCERIN TD PATCH 24HR
321000		Nitroglycerin TL SPRAY SPRAY)	NITROGLYCERIN TL
321000		Nitroglycerin TD Patch HR HR	NITROGLYCERIN TRANSDERMAL
321000		Nitroglycerin IV in D W	NITROGLYCERIN/IN
321000		Nitroglycerin CR	NITROGLYN
321000		Nitroglycerin	NITROL
321000		Nitroglycerin TL Aerosol DOSE	NITROLINGUAL
321000		Nitroglycerin TL SPRAY SPRAY)	NITROLINGUAL PUMPSPRAY
321000		Nitroglycerin SL	NITROQUICK
321000		Nitroglycerin SL	NITROSTAT
321000		Nitroglycerin SL	NITROTAB
321000		Isosorbide Dinitrate	THSC ISOSORBIDE DINITRATE
321000		Nitroglycerin TD Patch HR HR	TRANSDERM-NITRO
321000		Nitroglycerin TD Patch HR HR	TRANSDERMAL-NTG
321000		Nitroglycerin IV	TRIDIL
	BETA BLOCKERS/*Beta Blockers Non-Selective**		
331000		Sotalol HCl	BETAPACE
331000		Sotalol HCl	BETAPACE AF

APPENDIX C. EXCLUSIONS BASED ON MEDICATIONS (continued)

Class Code	Class Name	Generic	Drug Name
	BETA BLOCKERS/*Beta Blockers Non-Selective**		
331000		Timolol Maleate	BLOCADREN
331000		Carteolol HCl	CARTEOLOL HCL
331000		Carteolol HCl	CARTROL
331000		Carvedilol	CARVEDILOL
331000		Carvedilol	COREG
331000		Nadolol	CORGARD
331000		Propranolol HCl	INDERAL
331000		Propranolol HCl CR	INDERAL LA
331000		Propranolol HCl Sustained-Release Beads SR HR	INNOPRAN XL
331000		Penbutolol Sulfate	LEVATOL
331000		Nadolol	NADOLOL
331000		Penbutolol Sulfate	PENBUTOLOL SULFATE
331000		Pindolol	PINDOLOL
331000		Propranolol HCl	PROPRANOLOL HCL
331000		Propranolol HCl Conc	PROPRANOLOL HCL CONC
331000		Propranolol HCl CR	PROPRANOLOL HCL CR
331000		Propranolol HCl CR	PROPRANOLOL HCL ER
331000		Propranolol HCl Conc	PROPRANOLOL HCL INTENSOL
331000		Propranolol HCl CR	PROPRANOLOL HCL LA
331000		Propranolol HCl Oral	PROPRANOLOL HCL ORAL
331000		Propranolol HCl Sustained-Release Beads SR HR	PROPRANOLOL HCL SUSTAINED- RELEASE BEADS SR 24HR
331000		Propranolol HCl CR	PROPRANOLOL LA
331000		Sotalol HCl	SORINE
331000		Sotalol HCl	SOTALOL AF
331000		Sotalol HCl	SOTALOL HCL
331000		Propranolol HCl	THSC PROPRANOLOL HCL
331000		Timolol Maleate	TIMOLOL MALEATE
331000		Pindolol	VISKEN
332000		Acebutolol HCl	ACEBUTOLOL HCL
332000		Atenolol	ATENOLOL
332000		Betaxolol HCl	BETAXOLOL HCL
332000		Bisoprolol Fumarate	BISOPROLOL FUMARATE
332000		Esmolol HCl	BREVIBLOC
332000		Esmolol HCl	ESMOLOL HCL
332000		Esmolol HCl-Sodium Chloride IV	ESMOLOL HCL-SODIUM CHLORIDE IV
332000		Betaxolol HCl	KERLONE

APPENDIX C. EXCLUSIONS BASED ON MEDICATIONS (continued)

Class Code	Class Name	Generic	Drug Name
	BETA BLOCKERS/*Beta Blockers Non-Selective**		
332000		Metoprolol Tartrate	LOPRESSOR
332000		Metoprolol Succinate SR HR	METOPROLOL SUCCINATE SR 24HR
332000		Metoprolol Tartrate	METOPROLOL TARTRATE
332000		Acebutolol HCl	SECTRAL
332000		Atenolol	TENORMIN
332000		Atenolol	THSC ATENOLOL
332000		Metoprolol Tartrate	THSC METOPROLOL TARTRATE
332000		Metoprolol Succinate SR HR	TOPROL XL
332000		Bisoprolol Fumarate	ZEBETA
333000		Labetalol HCl	LABELALOL HCL
333000		Labetalol HCl IV	LABELALOL HCL IV
333000		Labetalol HCl	NORMODYNE
333000		Labetalol HCl	TRANDATE
333000		Labetalol HCl IV	TRANDATE IV
	ANTIARRHYTHMIC/*Antiarrhythmics Type I - Nonspecific**		
350500		Moricizine HCl	ETHMOZINE
350500		Moricizine HCl	MORICIZINE HCL
	ANTIARRHYTHMIC/*Antiarrhythmics Type I-A**		
351000		Disopyramide Phosphate	DISOPYRAMIDE PHOSPHATE
351000		Disopyramide Phosphate CR	DISOPYRAMIDE PHOSPHATE CR
351000		Disopyramide Phosphate CR	DISOPYRAMIDE PHOSPHATE ER
351000		Disopyramide Phosphate	NORPACE
351000		Disopyramide Phosphate CR	NORPACE CR
351000		Procainamide HCl	PROCAINAMIDE HCL
351000		Procainamide HCl CR	PROCAINAMIDE HCL CR
351000		Procainamide HCl CR	PROCAINAMIDE HCL ER
351000		Procainamide HCl	PROCAINAMIDE HCL MDV
351000		Procainamide HCl CR	PROCAINAMIDE HCL SR
351000		Procainamide HCl SR HR	PROCAINAMIDE HCL SR 12HR
351000		Procainamide HCl SR HR	PROCANBID
351000		Procainamide HCl	PRONESTYL
351000		Procainamide HCl CR	PRONESTYL SR
351000		Quinidineluconate CR	QUINAGLUTE
351000		Quinidine Sulfate CR	QUINIDEX EXTENTABS
351000		Quinidineluconate	QUINIDINE GLUCONATE
351000		Quinidineluconate CR	QUINIDINE GLUCONATE CR
351000		Quinidineluconate CR	QUINIDINE GLUCONATE ER
351000		Quinidineluconate CR	QUINIDINE GLUCONATE SA

APPENDIX C. EXCLUSIONS BASED ON MEDICATIONS (continued)

Class Code	Class Name	Generic	Drug Name
	ANTIARRHYTHMIC/*Antiarrhythmics Type I-A**		
351000		Quinidineluconate CR	QUINIDINE GLUCONATE SR
351000		Quinidine Sulfate	QUINIDINE SULFATE
351000		Quinidine Sulfate CR	QUINIDINE SULFATE CR
351000		Quinidine Sulfate CR	QUINIDINE SULFATE ER
351000		Quinidine Sulfate	THSC QUINIDINE SULFATE
	ANTIARRHYTHMIC/*Antiarrhythmics Type I-B**		
352000		Lidocaine IV Infusion in D W	LIDOCAINE HCL /D5W
352000		Lidocaine IV Infusion in D W	LIDOCAINE HCL IN D5W
352000		Lidocaine HCl IV	LIDOCAINE HCL IV
352000		Lidocaine HCl IV Admixture	LIDOCAINE HCL IV ADMIXTURE
352000		Lidocaine HCl IV Admixture	LIDOCAINE HCL PTV
352000		Lidocaine IV Infusion in D W	LIDOCAINE IV INFUSION IN D5W
352000		Mexiletine HCl	MEXILETINE HCL
352000		Mexiletine HCl	MEXITIL
352000		Tocainide HCl	TOCAINIDE HCL
352000		Tocainide HCl	TONOCARD
	ANTIARRHYTHMIC/*Antiarrhythmics Type I-C**		
353000		Flecainide Acetate	FLECAINIDE ACETATE
353000		Propafenone HCl	PROPAFENONE HCL
353000		Propafenone HCl	RYTHMOL
353000		Flecainide Acetate	TAMBOCOR
	ANTIARRHYTHMIC/*Antiarrhythmics Type III**		
354000		Amiodarone HCl	AMIODARONE HCL
354000		Bretylum Tosylate	BRETYLIUM TOSYLATE
354000		Bretylum Tosylate in D W	BRETYLIUM TOSYLATE IN D5W
354000		Bretylum Tosylate	BRETYLIUM TOSYLATE SDV
354000		Bretylum Tosylate in D W	BRETYLIUM TOSYLATE/D5W
354000		Amiodarone HCl	CORDARONE
354000		Amiodarone HCl	CORDARONE I.V.
354000		Ibutilide Fumarate	CORVERT
354000		Dofetilide	DOFETILIDE
354000		Ibutilide Fumarate	IBUTILIDE FUMARATE
354000		Amiodarone HCl	PACERONE
354000		Dofetilide	TIKOSYN
	ANTIARRHYTHMIC/*Misc. Antiarrhythmic**		
355000		Adenosine IV	ADENOCARD

APPENDIX C. EXCLUSIONS BASED ON MEDICATIONS (continued)

Class Code	Class Name	Generic	Drug Name
	ANTIHYPERTENSIVE/*Antihypertensive Combinations**/*Beta Blocker & Diuretic Combinations***		
369920		Atenolol & Chlorthalidone	ATENOLOL & CHLORTHALIDONE
369920		Atenolol & Chlorthalidone	ATENOLOL/CHLORTHALIDONE
369920		Bisoprolol & Hydrochlorothiazide	BISOPROLOL & HYDROCHLOROTHIAZIDE
369920		Bisoprolol & Hydrochlorothiazide	BISOPROLOL FUMARATE & HYDROCHLOROTHIAZIDE
369920		Bisoprolol & Hydrochlorothiazide	BISOPROLOL FUMARATE/HCTZ
369920		Bisoprolol & Hydrochlorothiazide	BISOPROLOL/HCTZ
369920		Nadolol & Bendroflumethiazide	CORZIDE
369920		Propranolol & Hydrochlorothiazide	INDERIDE
369920		Propranolol & Hydrochlorothiazide CR	INDERIDE LA
369920		Metoprolol & Hydrochlorothiazide	LOPRESSOR HCT
369920		Metoprolol & Hydrochlorothiazide	METOPROLOL & HYDROCHLOROTHIAZIDE
369920		Nadolol & Bendroflumethiazide	NADOLOL & BENDROFLUMETHIAZIDE
369920		Propranolol & Hydrochlorothiazide	PROPRANOLOL & HYDROCHLOROTHIAZIDE
369920		Propranolol & Hydrochlorothiazide CR	PROPRANOLOL & HYDROCHLOROTHIAZIDE CR
369920		Propranolol & Hydrochlorothiazide	PROPRANOLOL/HYDROCHLOROTHIAZIDE
369920		Atenolol & Chlorthalidone	TENORETIC
369920		Timolol & Hydrochlorothiazide	TIMOLIDE
369920		Timolol & Hydrochlorothiazide	TIMOLOL & HYDROCHLOROTHIAZIDE
369920		Bisoprolol & Hydrochlorothiazide	ZIAC
	OPHTHALMIC/*Beta-blockers - Ophthalmic**		
862500		Levobunolol HCl Ophth	BETAGAN
862500		Levobunolol HCl Ophth	BETAGAN C BID
862500		Levobunolol HCl Ophth	BETAGAN C QD
862500		Levobunolol HCl Ophth	BETAGAN WITHOUT C
862500		Betaxolol HCl Ophth	BETAXOLOL HCL OPHTH
862500		Timolol Ophth	BETIMOL
862500		Betaxolol HCl Ophth	BETOPTIC
862500		Betaxolol HCl Ophth	BETOPTIC-S
862500		Carteolol HCl Ophth	CARTEOLOL HCL OPHTH

APPENDIX C. EXCLUSIONS BASED ON MEDICATIONS (continued)

Class Code	Class Name	Generic	Drug Name
	OPHTHALMIC/*Beta-blockers - Ophthalmic**		
862500		Levobunolol HCl Ophth	LEVOBUNOLOL HCL
862500		Levobunolol HCl Ophth	LEVOBUNOLOL HCL OPHTH
862500		Metipranolol Ophth	METIPRANOLOL
862500		Metipranolol Ophth	METIPRANOLOL OPHTH
862500		Carteolol HCl Ophth	OCUPRESS
862500		Metipranolol Ophth	OPTIPRANOLOL
862500		Timolol Maleate Ophth	TIMOLOL MALEATE OPHTH
862500		Timolol Maleate Ophthming	TIMOLOL MALEATE OPHTHALMICMING
862500		Timolol Maleate Ophthming	TIMOLOL MALEATE OPHTHMING
862500		Timolol Ophth	TIMOLOL OPHTH
862500		Timolol Maleate Ophth	TIMOPTIC
862500		Timolol Maleate Ophthming	TIMOPTIC-XE
	OPHTHALMIC/*Beta-blockers - Ophthalmic**/*Beta-blockers - Combinations***		
862599		Dorzolamide-Timolol Ophth (Base Equiv)	COSOPT
862599		Dorzolamide-Timolol Ophth (Base Equiv)	DORZOLAMIDE-TIMOLOL OPHTH

**APPENDIX D
PHYSICAL ACTIVITY
READINESS CODE**

APPENDIX D. PHYSICAL ACTIVITY READINESS CODE

Physical Activity Readiness Questions – Level 1 (Standard Script)	
English	Spanish
I am going to ask you several questions to describe your typical physical activity level . Please try to answer as accurately as possible. Please wait until I read all three questions before you give me your answer.	Le voy a hacer varias preguntas para describir su nivel típico de actividad física . Por favor trate de responder tan precisamente como sea posible. Por favor espere hasta que yo lea las tres preguntas antes de darme su respuesta.
1. Would you say that you did little or no regular recreation, sport, or physical activity? OR	1. Diría que usted hizo poca o ninguna actividad regular de recreación, deporte, o física? O
2. Would you say that you participated regularly in recreation <u>or work</u> requiring modest physical activity ? OR	2. ¿Diría que usted participó regularmente en recreación <u>o trabajo</u> que requería actividad física moderada ? O
3. Would you say that you participated regularly in heavy physical exercise ?	3. ¿Diría que usted participó regularmente en ejercicios físicos pesados ?
Modest physical activities include: walking, calisthenics, bowling, weight lifting, yard work.	Actividades físicas moderadas incluye: caminar, calistenia, bolos, levantamiento de pesas, trabajo en el (patio/jardín).
Heavy physical activities include jogging, swimming, cycling, rowing, tennis, and basketball.	Actividades físicas pesadas incluye: trotar, nadar, andar en bicicleta, remar, jugar tenis, y baloncesto.
Physical Activity Readiness Questions – Level 2 - Little/No Activity (Standard Script)	
English	Spanish
1. Would you say that you avoid walking or exertion (for example, always use the elevator, drive whenever possible instead of walking.)? OR	1. ¿Diría que usted evita caminar o hacer esfuerzos (por ejemplo, siempre toma el ascensor, conduce en lugar de caminar cada vez que es posible.)? O
2. Would you say that you walk for pleasure, routinely use stairs, occasionally exercise sufficiently to cause heavy breathing or perspiration?	2. ¿Diría que usted camina por placer, rutinariamente usa las escaleras, ocasionalmente hace ejercicio suficientemente como para que le cause respiración agitada o transpiración?

Physical Activity Readiness Questions – Level 2 - Moderate Activity (Standard Script)	
English	Spanish
Would you say that you participated regularly in recreation or modest physical activity for:	¿Diría que usted participó regularmente en actividades de recreación o físicas moderadas por:
1. 10 to 60 minutes per week? OR	1. <u>10 a 60 minutos por semana?</u> O
2. More than 60 minutes per week?	2. <u>Más de 60 minutos por semana?</u>
Physical Activity Readiness Questions – Level 2 – Heavy Activity (Standard Script)	
English	Spanish
Now I am going to ask for some more detail on the <u>amount</u> of heavy physical exercise you did. I am going to give you four options.	Ahora le voy a preguntar algunos detalles más sobre la <u>cantidad</u> de ejercicio físico pesado que usted hizo. Le voy a dar cuatro opciones.
Would you say that you participated regularly in heavy physical activity for:	¿Diría que usted participó regularmente en actividades físicas pesadas ...
1. less than 30 minutes per week OR	1. menos de 30 minutos por semana, O
2. 30 to 60 minutes per week OR	2. 30 a 60 minutos por semana, O
3. 1 to 3 hours per week OR	3. 1 a 3 horas por semana, O
4. more than 3 hours per week OR	4. más de 3 horas por semana?

Determination of PAR code from responses

The PAR code is one of the determinants of which treadmill protocol will be assigned to the SP. PAR codes range from 0 to 7. The code is assigned as follows:

If the SP reports little or no regular recreation, sport, or physical activity and avoids walking or exertion, PAR code = 0

If the SP reports little or no regular recreation, sport, or physical activity and walks for pleasure, routinely uses stairs, occasionally exercises sufficiently to cause heavy breathing or perspiration, PAR code =1

If the SP reports participating regularly in recreation or work requiring modest physical activity for 10-60 minutes per week, PAR code = 2

If the SP reports participating regularly in recreation or work requiring modest physical activity for more than 60 minutes per week, PAR code =3

If the SP reports participating regularly in heavy physical exercise for less than 30 minutes per week, PAR code = 4

If the SP reports participating regularly in heavy physical exercise for 30-60 minutes per week, PAR code = 5

If the SP reports participating regularly in heavy physical exercise for 1-3 hours per week, PAR code = 6

If the SP reports participating regularly in heavy physical exercise for more than 3 hours per week, PAR code = 7

Sources:

Jackson, Blair, Mahar, Wier, Ross, and Stuteville. (1990). Prediction of functional aerobic capacity without exercise testing. *Medicine and Science in Sports and Exercise*, 22 (6), 863-870.

Ross and Jackson. (1990). *Exercise Concepts, Calculations and Computer Applications*. Benchmark Press.

APPENDIX E
REVIEW OF EDIT CRITERIA

APPENDIX E. REVIEW OF EDIT CRITERIA

Entire Exam (these criteria apply throughout the entire exam):

- %PMHR greater than 100% Go to recovery (no exceptions)
- %PMHR greater than 85%
(19 through 49 years) Check RPE and if SP is OK based on criteria,
continue.
- %PMHR greater than 90%
(12 through 18 years) Check RPE and if SP is OK based on criteria,
continue.
- SBP greater than 260 mmHg Go to recovery (no exceptions)
- DBP greater than 115 mm Hg Go to recovery (no exceptions)
- RPE greater than 17 Go to recovery (exception at end of Stage 2)

Warmup

- %PMHR less than 50% Increase exercise protocol
- %PMHR greater than 60% Decrease exercise protocol
- Criteria for 'Entire Exam' also apply Go to recovery

Stage 1

- %PMHR greater than 80% Check RPE and if SP is OK based on criteria,
continue.
- Criteria for 'Entire Exam' also apply Check RPE and if SP is OK based on criteria,
continue.
- RPE >17 Check if SP understands concept of RPE. Go to
recovery only if RPE actually is >17.

Stage 2

- %PMHR greater than 85%
(19 through 49 years) Check RPE and if SP is OK based on criteria,
continue.
- %PMHR greater than 90%
(12 through 18 years) Check RPE and if SP is OK based on criteria,
continue.
- Criteria for 'Entire Exam' also apply Check RPE and if SP is OK based on criteria,

APPENDIX F
CALCULATION OF PREDICTED VO₂ MAX

APPENDIX F. CALCULATION OF PREDICTED VO₂ MAX

Predicted VO₂ max = 56.363 + [1.921 * (PA-R)] – [0.381 * (Age at interview)] – [0.754 * (BMI)] + [10.987 * (F=0, M=1)]

PAR Code (as determined from Appendix E)	Code 0-7
Use Age at Interview	years
Measured body weight	Kg.
Measured body height	cm.
BMI (body mass index) = body weight (kg)/height squared (meters)	(kg/m ²)

Use Table in Appendix H to determine protocol based on predicted VO₂ max calculated above.

APPENDIX G
CALCULATION OF ESTIMATED VO₂ MAX

APPENDIX G. CALCULATION OF ESTIMATED VO₂ MAX

Because the relation between heart rate and oxygen consumption is linear during exercise, we can estimate maximal oxygen consumption (VO₂ max) by measuring the heart rate response to known levels of submaximal work. This relation can be summed up by the equation for a line: $y = mx + b$, where y is heart rate, m is slope, x is VO₂, and b is the intercept. By rearranging these terms, we can derive the following equation:

$$\text{Estimated VO}_2\text{max} = \frac{\text{PMHR} - \text{Intercept}}{\text{Slope}}$$

$$\begin{aligned} \text{Slope} &= n(\sum x_i y_i) - (\sum x_i)(\sum y_i) / n \sum x_i^2 - (\sum x_i)^2 \\ \text{PMHR} &= 220 - \text{Age at interview} \\ \text{Intercept} &= \bar{Y} - b\bar{X} \end{aligned}$$

\bar{Y} = mean of End of Stage 1 Heart Rate + End of Stage 2 Heart Rate

\bar{X} = mean of End of Stage 1 VO₂ + End of Stage 2 VO₂

b = slope

$$\text{Slope} = n(\sum x_i y_i) - (\sum x_i)(\sum y_i) / n \sum x_i^2 - (\sum x_i)^2$$

$$n = 2$$

$$x_i = x_1, x_2$$

$$x_1 = \text{submax VO}_2 \text{ at end of Stage 1}$$

$$x_2 = \text{submax VO}_2 \text{ at end of Stage 2}$$

$$y_i = y_1, y_2$$

$$y_1 = \text{end of Stage 1 HR}$$

$$y_2 = \text{end of Stage 2 HR}$$

Get end of stage VO₂ from Appendix H.

Example: A 40 year old man was assigned Protocol 6. Looking in Appendix G, we see that the corresponding submax VO₂ values for these stages are 23.3 and 31.4 ml/kg/min respectively. His heart rate at the end of Stage 1 is 120 and at the end of Stage 2 is 140 beats/min respectively. Plugging these numbers into the formulas above, we then solve our equation.

$$\text{Estimated VO}_2 \text{ max} = \frac{180 - 62.47}{2.469} = 47.6 \text{ ml/kg/min}$$

APPENDIX H
DETERMINATION OF EXERCISE PROTOCOL

APPENDIX H. DETERMINATION OF EXERCISE PROTOCOL

Exercise Protocol Number	WARMUP				STAGE 1			STAGE 2			RECOVERY		
	Predicted VO ₂ max (ml/kg/min)	Speed (mph)	Grade (%)	% predicted VO ₂ Max	Speed (mph)	Grade (%)	% predicted VO ₂ Max (ml/kg/min)	Speed (mph)	Grade (%)	% predicted VO ₂ Max (ml/kg/min)	Speed (mph)	Grade (%)	% predicted VO ₂ Max (ml/kg/min)
1	<20	1.7	0	45(8.1)	2.1	0.5	55%(9.6)	2.1	4.5%	76(13.6)	2.0	0	49(8.9)
2	20-24	2.0	1	45(10)	2.3	2.0	55(11.9)	2.3	6.5%	75(16.9)	2.0	0	41(8.9)
3	25-29	2.2	2	45(11.5)	2.7	3.0	55(14.6)	2.7	7.5%	75(20.6)	2.0	0	33(8.9)
4	30-34	2.7	2	45(13.3)	3.1	4.0	55(17.8)	3.1	8.5%	75(24.4)	2.0	0	28(8.9)
5	35-39	3.0	3	45(16)	3.7	4.0	55(20.6)	3.7	8.0%	75(27.8)	2.0	0	24(8.9)
6	40-44	3.1	3.5	45(17)	3.7	5.5	55 (23.3)	3.7	10%	75(31.4)	2.0	0	21(8.9)
7	45-49	3.2	5	45(19.8)	3.7	7.0	55(26.0)	3.7	12.5%	75(35.9)	2.0	0	19(8.9)
8	>50	3.6	5	45(21.8)	3.7	8.5	55(28.7)	3.7	14.5%	75(39.5)	2.0	0	17(8.9)

I-H

Protocol Number number to identify protocol being used (see table)
 Speed miles per hour
 Grade percent incline
 % predicted VO₂ max predicted VO₂ max as % (submaximal VO₂ in ml/kg/min in parenthesis)

APPENDIX I
REFERENCE RANGES FOR VO₂ MAX

APPENDIX I. REFERENCE RANGES FOR VO₂ MAX

Males ages 12-19

Low	< 42
Moderate	42 – 51.99
High	≥ 52

Females ages 12

Low	<37
Moderate	37-45.99
High	≥ 46

Females ages 13

Low	<36
Moderate	36-44.99
High	≥ 45

Females ages 14

Low	<35
Moderate	35-43.99
High	≥ 44

Females ages 15-19

Low	<35
Moderate	35 – 42.99
High	≥ 43

Males ages 20-29

Low	≤ 37.13
Moderate	37.14-44.22
High	≥ 44.23

Females ages 20-29

Low	≤ 30.63
Moderate	30.64-36.64
High	≥ 36.64

Males ages 30-39

Low	≤ 35.35
Moderate	35.36-42.41
High	≥ 42.42

Females ages 30-39

Low	≤ 28.70
Moderate	28.71-34.59
High	≥ 34.60

Males ages 40-49

Low	≤ 33.04
Moderate	33.05-39.88
High	≥ 39.89

Females ages 40-49

Low	≤ 26.54
Moderate	26.55-32.30
High	≥ 32.31

The level of cardiovascular fitness is categorized based on gender-age specific cut-points of estimated VO₂ max. The reference cut-points used for adults 20-49 years are based on data from the Aerobics Center Longitudinal Study (ACLS).^{1,2} Low level of CV fitness is defined as an estimated VO₂ max below the 20th percentile of the ACLS data of the same gender and age group; moderate fitness is defined as a value between the 20th and 59th percentile, and high fitness level is defined as at or above the 60th percentile. The reference standards used for adolescents and young adults 12-19 years are based on the criteria used in the FITNESSGRAM program.^{3,4}

Report of Findings statement: “Compared with other people of your age and sex, your cardiovascular fitness level is *<low, moderate, high>*.”

References

1. American College of Sports Medicine. (1995). *ACSM's Guidelines for Exercise Testing and Prescription*, 6th edition. Philadelphia, PA: Lippincott Williams and Wilkins Company.
2. Blair, S.N., Kohl, H.W. 3rd, Paffenbarger, R.S. Jr., et al. (1989). *Physical Fitness and All-Cause Mortality. A Prospective Study of Healthy Men and Women*. JAMA, 262(17), 2395-401.
3. Cureton, K.J. and Warren, G.L. (1990). *Criterion-Referenced Standards for Youth Health-Related Fitness Tests: A Tutorial*. Research Quarterly for Exercise and Sport, 61(1), 7-19.
4. Cureton, K.J. and Plowman, S.A. (1999). *Aerobic Capacity Assessments*. In Welk G.J., Morrow, J.R. Jr., and Falls H.B. (Ed.) *Fitnessgram Reference Guide* (pp. 66-86). Dallas, TX: Cooper Institute. Available at: <http://dev.cooperinst.org/shopping/PDF%20format/Fitnessgram%20Reference%20Guide.pdf>

APPENDIX J
SPEED & GRADE TABLE BY PROTOCOL & STAGE

APPENDIX J. SPEED AND GRADE TABLE BY PROTOCOL AND STAGE

Protocol #	Stage	Current/ Lower/ Higher	Grade (%)	Speed (mph)	Protocol #	Stage	Current/ Lower/ Higher	Grade (%)	Speed (mph)
1	Warm-up	Current (1)	0%	1.7	2	Warm-up	Current (2)	1.0%	2.0
1	Stage 1	Current (1)	0.5%	2.1	2	Stage 1	Current (2)	2.0%	2.3
1	Stage 2	Current (1)	4.5%	2.1	2	Stage 2	Current (2)	6.5%	2.3
1	Recovery	Current (1)	0%	2.0	2	Recovery	Current (2)	0%	2.0
1	Stage 1	Lower (0)	0%	0.8	2	Stage 1	Lower (1)	0.5%	2.1
1	Stage 2	Lower (0)	0%	0.8	2	Stage 2	Lower (1)	4.5%	2.1
1	Recovery	Lower (0)	0%	0.8	2	Recovery	Lower (1)	0%	2.0
1	Stage 1	Higher (2)	2.0%	2.3	2	Stage 1	Higher (3)	3.0%	2.7
1	Stage 2	Higher (2)	6.5%	2.3	2	Stage 2	Higher (3)	7.5%	2.7
1	Recovery	Higher (2)	0%	2.0	2	Recovery	Higher (3)	0%	2.0
1	Stage 1	Lower (0)	0%	0.8	2	Stage 1	Lower (1)	0.5%	2.1
1	Stage 2	Lower (0)	0%	0.8	2	Stage 2	Lower (1)	4.5%	2.1
1	Recovery	Lower (0)	0%	0.8	2	Recovery	Lower (1)	0%	2.0
1	Stage 1	Higher (2)	2.0%	2.3	2	Stage 1	Higher (3)	3.0%	2.7
1	Stage 2	Higher (2)	6.5%	2.3	2	Stage 2	Higher (3)	7.5%	2.7
1	Recovery	Higher (2)	0%	2.0	2	Recovery	Higher (3)	0%	2.0
3	Warm-up	Current (3)	2.0%	2.2	4	Warm-up	Current (4)	2.0%	2.7
3	Stage 1	Current (3)	3.0%	2.7	4	Stage 1	Current (4)	4.0%	3.1
3	Stage 2	Current (3)	7.5%	2.7	4	Stage 2	Current (4)	8.5%	3.1
3	Recovery	Current (3)	0%	2.0	4	Recovery	Current (4)	0%	2.0
3	Stage 1	Lower (2)	2.0%	2.3	4	Stage 1	Lower (3)	3.0%	2.7
3	Stage 2	Lower (2)	6.5%	2.3	4	Stage 2	Lower (3)	7.5%	2.7
3	Recovery	Lower (2)	0%	2.0	4	Recovery	Lower (3)	0%	2.0
3	Stage 1	Higher (4)	4.0%	3.1	4	Stage 1	Higher (5)	4.0%	3.7
3	Stage 2	Higher (4)	8.5%	3.1	4	Stage 2	Higher (5)	8.0%	3.7
3	Recovery	Higher (4)	0%	2.0	4	Recovery	Higher (5)	0%	2.0
3	Stage 1	Lower (2)	2.0%	2.3	4	Stage 1	Lower (3)	3.0%	2.7
3	Stage 2	Lower (2)	6.5%	2.3	4	Stage 2	Lower (3)	7.5%	2.7
3	Recovery	Lower (2)	0%	2.0	4	Recovery	Lower (3)	0%	2.0
3	Stage 1	Higher (4)	4.0%	3.1	4	Stage 1	Higher (5)	4.0%	3.7
3	Stage 2	Higher (4)	8.5%	3.1	4	Stage 2	Higher (5)	8.0%	3.7
3	Recovery	Higher (4)	0%	2.0	4	Recovery	Higher (5)	0%	2.0

APPENDIX J. SPEED AND GRADE TABLE BY PROTOCOL AND STAGE (continued)

Protocol #	Stage	Current/ Lower/ Higher	Grade (%)	Speed (mph)	Protocol #	Stage	Current/ Lower/ Higher	Grade (%)	Speed (mph)
5	Warm-up	Current (5)	3.0%	3.0	6	Warm-up	Current (6)	3.5%	3.1
5	Stage 1	Current (5)	4.0%	3.7	6	Stage 1	Current (6)	5.5%	3.7
5	Stage 2	Current (5)	8.0%	3.7	6	Stage 2	Current (6)	10.0%	3.7
5	Recovery	Current (5)	0%	2.0	6	Recovery	Current (6)	0%	2.0
5	Stage 1	Lower (4)	4.0%	3.1	6	Stage 1	Lower (5)	4.0%	3.7
5	Stage 2	Lower (4)	8.5%	3.1	6	Stage 2	Lower (5)	8.0%	3.7
5	Recovery	Lower (4)	0%	2.0	6	Recovery	Lower (5)	0%	2.0
5	Stage 1	Higher (6)	5.5%	3.7	6	Stage 1	Higher (7)	7.0%	3.7
5	Stage 2	Higher (6)	10.0%	3.7	6	Stage 2	Higher (7)	12.5%	3.7
5	Recovery	Higher (6)	0%	2.0	6	Recovery	Higher (7)	0%	2.0
5	Stage 1	Lower (4)	4.0%	3.1	6	Stage 1	Lower (5)	4.0%	3.7
5	Stage 2	Lower (4)	8.5%	3.1	6	Stage 2	Lower (5)	8.0%	3.7
5	Recovery	Lower (4)	0%	2.0	6	Recovery	Lower (5)	0%	2.0
5	Stage 1	Higher (6)	5.5%	3.7	6	Stage 1	Higher (7)	7.0%	3.7
5	Stage 2	Higher (6)	10.0%	3.7	6	Stage 2	Higher (7)	12.5%	3.7
5	Recovery	Higher (6)	0%	2.0	6	Recovery	Higher (7)	0%	2.0
7	Warm-up	Current (7)	5.0%	3.2	8	Warm-up	Current (8)	5.0%	3.6
7	Stage 1	Current (7)	7.0%	3.7	8	Stage 1	Current (8)	8.5%	3.7
7	Stage 2	Current (7)	12.5%	3.7	8	Stage 2	Current (8)	14.5%	3.7
7	Recovery	Current (7)	0%	2.0	8	Recovery	Current (8)	0%	2.0
7	Stage 1	Lower (6)	5.5%	3.7	8	Stage 1	Lower (7)	7.0%	3.7
7	Stage 2	Lower (6)	10.0%	3.7	8	Stage 2	Lower (7)	12.5%	3.7
7	Recovery	Lower (6)	0%	2.0	8	Recovery	Lower (7)	0%	2.0
7	Stage 1	Higher (8)	8.5%	3.7	8	Stage 1	Higher (9)	0%	0.8
7	Stage 2	Higher (8)	14.5%	3.7	8	Stage 2	Higher (9)	0%	0.8
7	Recovery	Higher (8)	0%	2.0	8	Recovery	Higher (9)	0%	0.8
7	Stage 1	Lower (6)	5.5%	3.7	8	Stage 1	Lower (7)	7.0%	3.7
7	Stage 2	Lower (6)	10.0%	3.7	8	Stage 2	Lower (7)	12.5%	3.7
7	Recovery	Lower (6)	0%	2.0	8	Recovery	Lower (7)	0%	2.0
7	Stage 1	Higher (8)	8.5%	3.7	8	Stage 1	Higher (9)	0%	0.8
7	Stage 2	Higher (8)	14.5%	3.7	8	Stage 2	Higher (9)	0%	0.8
7	Recovery	Higher (8)	0%	2.0	8	Recovery	Higher (9)	0%	0.8

APPENDIX K
SAMPLE DATA ENTRY SCREENS

APPENDIX K. SAMPLE DATA ENTRY SCREENS

Cardiovascular Fitness: Stand:410 Session:410911 11/17/2004 01:30 pm - 05:30 pm

SP ID: 485809 Name: OWENS 1, VIRGINIA Age: 44 years Gender: Female Date: 12/18/2004 Time: 03:50 PM

Shared Exclusion Questions

1a. Do you have any amputations of your legs and feet other than toes?

1b. Where is the amputation?

2. How much do you weigh without clothes or shoes? pounds

3. Do you have a pacemaker or automatic defibrillator?

4a. Are you currently pregnant?

4b. How many weeks? weeks Don't Know

1 of 9

End of Section Close Exam Finish

Cardiovascular Fitness: Stand:410 Session:410791 11/05/2004 01:30 pm - 05:30 pm

SP ID: 626223 Name: C, DAVID Age: 40 years Gender: Male Date: 12/17/2004 Time: 02:49 PM

Be All Question

Since you where interviewed in your home on 10/25/2004 have there been any changes in you health or medications that would prevent you from walking on a treadmill for the fitness test?

2 of 9

End of Section Close Exam Finish

Cardiovascular Fitness: Stand:410 Session:410911 11/17/2004 01:30 pm - 05:30 pm

SP ID: 485809 Name: OWENS 1, VIRGINIA Age: 44 years Gender: Female Date: 12/18/2004 Time: 03:50 PM

Blood Pressure

Meal
 Have you had any of the following in the past 30 minutes? (Check each that applies.)

- food
- alcohol
- coffee
- cigarettes

Arm/Cuff
 Arm selected: Right Left Could not obtain Cuff size:

Timer, min.

Pulse/MIL
 30 sec pulse: x 2 = Regular Irregular
 Maximum inflation level: mm Hg
 Could not obtain
 Pulse type:

3 of 9

End of Section Close Exam Finish

Reading 1

Systolic: mm Hg

Diastolic: mm Hg

Enhancement used

Could not obtain

Maximum inflation level: mm Hg

Reading 2

Systolic: mm Hg

Diastolic: mm Hg

Enhancement used

Could not obtain

Maximum inflation level: mm Hg

Reading 3

Systolic: mm Hg

Diastolic: mm Hg

Enhancement used

Could not obtain

Maximum inflation level: mm Hg

Average

Systolic: mm Hg

Diastolic: mm Hg

Maximum inflation level: mm Hg

Cardiovascular Fitness: Stand:410 Session:410911 11/17/2004 01:30 pm - 05:30 pm

SP ID: 485809 Name: OWENS 1, VIRGINIA Age: 44 years Gender: Female Date: 12/18/2004 Time: 03:50 PM

Blood Pressure Status

Status

Complete

Partial

Not Done

Comments

Other text

9 of 9

End of Section Close Exam Finish

Cardiovascular Fitness: Stand:107 Session:107012 07/06/1999 05:30 pm - 09:30 pm

SP ID: 818591 Name: BROWN, MAC Age: 38 years Gender: Male Date: 10/10/2000 Time: 12:48 PM

SP Height and Weight Information

Measured Weight: Kgs

Measured Height: Cms

◀◀ 1 ▶▶ of 10

End of Section Close Exam Finish

Cardiovascular Fitness Subsystem: Stand:806 Session:808559 12/10/1998 08:30 am - 12:30 pm

File View Utilities Reports Window Help

SP ID: 836308 Name: Anderson, Greg Age: 28 years Gender: Male Date: 01/03/1999 Time: 10:04 AM

Questions To Determine Exercise Protocol

I am going to ask you several questions to describe your TYPICAL PHYSICAL ACTIVITY LEVEL. Please try to answer as accurately as possible. Please wait until I read all three questions before you give me your answer.

1. Would you say that you did LITTLE or NO REGULAR recreation, sport, or physical activity?
OR
2. Would you say that you participated REGULARLY in recreation OR WORK requiring MODEST physical activity?
OR
3. Would you say that you participated REGULARLY in HEAVY physical activity?

If necessary use the following prompts to describe modest or heavy physical activity.
MODEST physical activities include: walking, calisthenics, bowling, weight lifting, yard work.
HEAVY physical activities include: jogging, swimming, cycling, rowing, tennis, basketball.

If SP's activity level over the last few months is different from their activity level in general, use the activity level which best describes their typical activity level over the last year.

If the SP is still not sure in which category they fall, (little or modest, modest or heavy), select the lower category.

Enter/Select answer:

1 of 8

End of Section Close Exam Finish

Ready

Cardiovascular Fitness Subsystem: Stand:806 Session:808559 12/10/1998 08:30 am - 12:30 pm

File View Utilities Reports Window Help

SP ID: 836308 Name: Anderson, Greg Age: 28 years Gender: Male Date: 01/03/1999 Time: 10:14 AM

Questions To Determine Exercise Protocol (Cont...)

1 Would you say that you AVOID walking or exertion, (for example, always use the elevator, drive whenever possible instead of walking.)?
OR

2 Would you say that you walk for pleasure, routinely use stairs, occasionally exercise sufficiently to cause heavy breathing or perspiration?

Would you say that you participated regularly in recreation or modest physical activity for:

1. 10 TO 60 MINUTES PER WEEK?
OR

2. MORE THAN 60 MINUTES PER WEEK?

Enter/Select answer: 1

2
Refused
Don't Know

2 of 8 End of Section Close Exam Finish

Ready

Cardiovascular Fitness Subsystem: Stand:806 Session:808559 12/10/1998 08:30 am - 12:30 pm

SP ID: 836308 Name: Anderson, Greg Age: 28 years Gender: Male Date: 01/03/1999 Time: 10:14 AM

Questions To Determine Exercise Protocol (Cont...)

1 Would you say that you AVOID walking or exertion, (for example, always use the elevator, drive whenever possible instead of walking.)?
OR

2 Would you say that you walk for pleasure, routinely use stairs, occasionally exercise sufficiently to cause heavy breathing or perspiration?

Would you say that you participated regularly in recreation or modest physical activity for:

1. 10 TO 60 MINUTES PER WEEK?
OR

2. MORE THAN 60 MINUTES PER WEEK?

Enter/Select answer:

2 of 8

End of Section Close Exam Finish

Cardiovascular Fitness: Stand:107 Session:107401 08/14/1999 01:30 pm - 05:30 pm

SP ID: 666259 Name: CHRISTIAN, TIM Age: 31 years Gender: Male Date: 09/26/2000 Time: 03:55 PM

Questions To Determine Exercise Protocol (Cont...)

Now I am going to ask for some more detail on the amount of heavy physical exercise you did. I am going to give you four options.

Would you say that you participated regularly in heavy physical activity for:

1. LESS THAN 30 MINUTES PER WEEK
OR
2. 30 TO 60 MINUTES PER WEEK
OR
3. 1 TO 3 HOURS PER WEEK
OR
4. MORE THAN 3 HOURS PER WEEK

Enter/Select answer:

4 of 10

End of Section Close Exam Finish

Cardiovascular Fitness Subsystem: Stand:806 Session:808559 12/10/1998 08:30 am - 12:30 pm

SP ID: 836308 Name: Anderson, Greg Age: 28 years Gender: Male Date: 01/03/1999 Time: 10:33 AM

Pretest Measurements

Room Temperature: Degrees

Exam Preparation

Arm:

Cuff Size:

Pretest Measurements

Heart Rate:

Systolic BP:

Diastolic BP:

4 of 8

Cardiovascular Fitness: Stand:107 Session:107341 08/08/1999 01:30 pm - 05:30 pm

SP ID: 132135 Name: MCCULLOUGH, KRISTINA MARIE Age: 16 years Gender: Female Date: 08/04/2000 Time: 01:31 PM

Treadmill Test

00:00
min sec

START

RESTART

EMERGENCY STOP

Change Protocol

Go To Recovery

Show Data

Vo2 Max: .00

Protocol	WARM-UP		STAGE 1		STAGE 2		RECOVERY	
	Speed	Grade	Speed	Grade	Speed	Grade	Speed	Grade
5	3.00	3.00	3.70	4.00	3.70	8.00	2.00	0
6	3.10	3.50	3.70	5.50	3.70	10.0	2.00	0
7	3.20	5.00	3.70	7.00	3.70	12.5	2.00	0

RPE

Captured HR

Manual HR

PMHR: 204.00 beats/min

%HR max

102 132.6 204

50% 60% 100%

5 of 9

End of Section Close Exam Finish

Cardiovascular Fitness: Stand:107 Session:107341 08/08/1999 01:30 pm - 05:30 pm

SP ID: 132135 Name: MCCULLOUGH, KRISTINA MARIE Age: 16 years Gender: Female Date: 08/04/2000 Time: 01:31 PM

Treadmill Test

00:30
min sec

START
RESTART
EMERGENCY STOP

Change Protocol
Go To Recovery
Show Data

Vo2 Max: .00

Protocol	WARM-UP		STAGE 1		STAGE 2		RECOVERY	
	Speed	Grade	Speed	Grade	Speed	Grade	Speed	Grade
5	3.00	3.00	3.70	4.00	3.70	8.00	2.00	0
6	3.10	3.50	3.70	5.50	3.70	10.0	2.00	0
7	3.20	5.00	3.70	7.00	3.70	12.5	2.00	0

RPE

Captured HR

Manual HR

PMHR: 204.00 beats/min

%HR max

102 132.6 204

50% 60% 100%

5 of 9

End of Section Close Exam Finish

Cardiovascular Fitness: Stand:250 Session:250140 10/20/2003 08:30 am - 12:30 pm

SP ID: 863711 Name: HART, CINDY Age: 34 years Gender: Female Date: 12/29/2003 Time: 08:34 AM

Treadmill Test

00:13
min sec

START
RESTART
EMERGENCY STOP

Change Protocol
Go To Recovery
Show Data

Protocol	WARM-UP		STAGE 1		STAGE 2		RECOVERY	
	Speed	Grade	Speed	Grade	Speed	Grade	Speed	Grade
4	2.70	2.00	3.10	4.00	3.10	8.50	2.00	0
5	3.00	3.00	3.70	4.00	3.70	8.00	2.00	0
6	3.10	3.50	3.70	5.50	3.70	10.0	2.00	0

RPE:

Captured HR:

Manual HR:

PMHR: 186.00 beats/min

%HR max: 111.6 148.8 186

Vo2 Max: .00

6 of 10

End of Section Close Exam Finish

Cardiovascular Fitness: Stand:250 Session:250140 10/20/2003 08:30 am - 12:30 pm

SP ID: 863711 Name: HART, CINDY Age: 34 years Gender: Female Date: 12/29/2003 Time: 08:34 AM

Treadmill Test

00:19
min sec

START
RESTART
EMERGENCY STOP

Change Protocol
Go To Recovery
Show Data

Protocol	WARM-UP		STAGE 1		STAGE 2		RECOVERY	
	Speed	Grade	Speed	Grade	Speed	Grade	Speed	Grade
4	2.70	2.00	3.10	4.00	3.10	8.50	2.00	0
5	3.00	3.00	3.70	4.00	3.70	8.00	2.00	0
6	3.10	3.50	3.70	5.50	3.70	10.0	2.00	0

RPE

Captured HR

Manual HR

PMHR: 186.00 beats/min 158.1 186

%HR max 85% 100%

6 of 10

End of Section Close Exam Finish

Cardiovascular Fitness: Stand:107 Session:107341 08/08/1999 01:30 pm - 05:30 pm

SP ID: 132135 Name: MCCULLOUGH, KRISTINA MARIE Age: 16 years Gender: Female Date: 08/04/2000 Time: 01:31 PM

Treadmill Test

02:04
min sec

START

RESTART

EMERGENCY STOP

Change Protocol

Go To Recovery

Show Data

Vo2 Max: .00

Protocol	WARM-UP		STAGE 1		STAGE 2		RECOVERY	
	Speed	Grade	Speed	Grade	Speed	Grade	Speed	Grade
5	3.00	3.00	3.70	4.00	3.70	8.00	2.00	0
6	3.10	3.50	3.70	5.50	3.70	10.0	2.00	0
7	3.20	5.00	3.70	7.00	3.70	12.5	2.00	0


RPE:

Captured HR:

Manual HR:

PMHR: beats/min 183.6 204

%HR max 90% 100%



5 of 9 End of Section Close Exam Finish

Cardiovascular Fitness: Stand:107 Session:107030 07/08/1999 08:30 am - 12:30 pm

SP ID: 855853 Name: HALL, JEFF D. Age: 12 years Gender: Female Date: 08/21/2000 Time: 03:04 PM

Treadmill Test

00:19
min sec

START

RESTART

EMERGENCY STOP

Change Protocol

Go To Recovery

Show Data

Vo2 Max: .00

Protocol	WARM-UP		STAGE 1		STAGE 2		RECOVERY	
	Speed	Grade	Speed	Grade	Speed	Grade	Speed	Grade
4	2.70	2.00	3.10	4.00	3.10	8.50	2.00	0
5	3.00	3.00	3.70	4.00	3.70	8.00	2.00	0
6	3.10	3.50	3.70	5.50	3.70	10.0	2.00	0

RPE:

Captured HR:

Manual HR:

PMHR: 208.00 beats/min 104 208

%HR max 50% 100%

5 of 9 End of Section Close Exam Finish

Cardiovascular Fitness Subsystem: Stand:806 Session:808559 12/10/1998 08:30 am - 12:30 pm

SP ID: 836308 Name: Anderson, Greg Age: 28 years Gender: Male Date: 01/03/1999 Time: 10:57 AM

Priority 1 Stopping Criteria

You have stopped the exam early. You must select one or more of the following stopping criteria:

- Pain or pressure in the chest
- Pain in neck, jaw, or teeth
- Pain in the shoulder or between the shoulder blades
- Pain radiating down one or both arms
- Moderate/severe leg pain or cramping
- Lightheadedness, dizziness
- Severe shortness of breath/wheezing
- Change in skin color to bluish/grayish
- Severe headache
- Subject appears confused or agitated
- Nausea
- Unstable gait
- Visual problems
- Other Priority 1

6 of 8

End of Section Close Exam Finish

Cardiovascular Fitness: Stand:250 Session:250100 10/16/2003 08:30 am - 12:30 pm

SP ID: 308832 Name: SATO, YOUME Age: 28 years Gender: Female Date: 12/29/2003 Time: 11:00 AM

Priority 2 Stopping Criteria

You have stopped the exam early. You must select one or more of the following stopping criteria:

- SP HR during Warm-up, Stage 1 or Stage 2 exceeds 90 percent for 12- through 18-year-olds or 85 percent PMHR for 19- through 49-year-olds and SP is unable to continue.
- SP HR exceeds 80 percent PMHR during Stage 1 and SP is unable to continue.
- SP HR exceeds 100% during Warm-up, Stage 1 or Stage 2
- Exercise blood pressure > 260 mmHg systolic and/or 115 mmHg diastolic
- Failure of systolic blood pressure to rise with increasing exercise intensity
- Significant drop (>20 mmHg) in systolic blood pressure during exercise
- Failure of heart rate to increase with increasing exercise intensity
- Sudden, noticeable variability in heart rate (sudden change of + 30 beats/minute during a STAGE)
- SP requests to stop test, or reports severe fatigue
- Failure of testing equipment
- SP is unable to stop gripping hand rails
- SP reports RPE > 17
- Technician discretion (tech notices signs of severe exertion).
- Other Enter Comment:

8 of 10

End of Section Close Exam Finish

Cardiovascular Fitness Subsystem: Stand:806 Session:808571 12/11/1998 05:30 pm - 09:30 pm

SP ID: 926247 Name: Ball, Jake Age: 37 years Gender: Male Date: 01/24/1999 Time: 06:51 PM

Cardiovascular Fitness Component Status

Status

Complete
 Partial
 Not Done

Comments

Other text

8 of 8

End of Section Close Exam Finish