
National Health
and Nutrition
Examination Survey

LOWER
EXTREMITY
DISEASE
PROCEDURES
MANUAL



January 2004

TABLE OF CONTENTS

<u>Chapter</u>		<u>Page</u>
1	OVERVIEW OF LOWER EXTREMITY DISEASE	1-1
	1.1 Observation of Abnormalities.....	1-1
	1.2 Peripheral Neuropathy	1-1
	1.3 Peripheral Vascular Disease	1-2
	1.4 LED in NHANES	1-3
2	EQUIPMENT/SUPPLIES/MATERIALS	2-1
	2.1 Description of Equipment.....	2-1
	2.1.1 5.07/10 Gram Sensory Testing Monofilament.....	2-1
	2.1.2 Two Alternative Forced Choice (2-AFC) Algorithm.....	2-1
	2.1.3 Parks Mini-Lab IV, Model 3100 (ABPI)	2-2
	2.1.4 Dual Frequency Bi-directional Doppler.....	2-6
	2.1.5 Blood Pressure Cuffs.....	2-6
	2.1.6 VIP Software.....	2-7
	2.1.7 Mercury Manometer with Y-Connector for Calibration Check.....	2-7
	2.2 Maintenance of Equipment.....	2-8
	2.2.1 5.07/10 Gram Sensory Testing Monofilament.....	2-8
	2.2.2 Parks Mini-Lab IV, Model 3100.....	2-8
	2.2.3 Mercury Sphygmomanometer (Used for Calibration Check).....	2-8
	2.3 Description of Supplies/Materials.....	2-9
	2.4 Calibration Check on Parks Mini-Lab	2-10
	2.5 Mercury Spills or Leaks.....	2-12
3	PROTOCOL	3-1
	3.1 Overview of LED Exam	3-1
	3.2 Introduction to Exam	3-1
	3.3 Safety/Exclusion Criteria.....	3-2
	3.4 Cuff Selection for ABPI	3-3
	3.5 Positioning for the LED Exam.....	3-4
	3.5.1 Brachial Cuff.....	3-5
	3.5.2 Ankle Cuffs	3-5

TABLE OF CONTENTS (continued)

<u>Chapter</u>		<u>Page</u>
3.6	Observation for Abnormalities	3-6
3.7	Monofilament Testing.....	3-9
	3.7.1 Explanation of the Test	3-9
	3.7.2 Sites to be Tested	3-11
	3.7.3 Order for Testing Sites	3-11
	3.7.4 Standard Procedures.....	3-11
	3.7.5 Definition of Responses	3-13
	3.7.6 Completing the Monofilament Test	3-15
3.8	Ankle Brachial Pressure Index (ABPI).....	3-16
	3.8.1 Explanation of the ABPI and Doppler	3-16
3.9	Locating the Doppler Pulse Sites.....	3-16
3.10	Preparing the Equipment for Measurement	3-18
	3.10.1 Preparing the Vascular Testing Device.....	3-18
	3.10.2 Preparing the VIP Software	3-19
3.11	Doppler Measurement of Pressures	3-20
3.12	Sequence of Taking Systolic Measurements	3-21
3.13	Deleting Data	3-21
3.14	Repeating Missed Measures	3-22
3.15	How the Mini-Lab Screen Displays the Cursor.....	3-22
3.16	Measurement of Systolic Pressures	3-23
3.17	Completion of Test	3-25
3.18	Examples of Lower Extremity Abnormalities	3-25
4	DATA ENTRY SCREENS.....	4-1
	4.1 Shared Exclusion Questions	4-1
	4.2 Exam Preparation.....	4-4
	4.3 Abnormality Observations.....	4-14
	4.3.1 Amputation.....	4-16
	4.3.2 Bunions	4-21
	4.3.3 Lesions	4-21
	4.4 Peripheral Neuropathy	4-24

TABLE OF CONTENTS (continued)

<u>Chapter</u>		<u>Page</u>
	4.4.1 Peripheral Neuropathy - Could Not Obtain.....	4-35
	4.4.2 Peripheral Neuropathy - Technical Problems	4-41
	4.4.3 End of Section 1 – Partial Status.....	4-45
	4.5 End of Section One – Section Status Screen (Complete)	4-47
	4.6 ABPI Data Capture	4-48
	4.7 VIP BP Screens.....	4-54
5	REFERRALS AND REPORT OF FINDINGS	5-1
	5.1 Observation Referrals	5-1
	5.2 Data Related Referrals for LED.....	5-5
	5.2.1 Definition of Referral Levels	5-5
	5.2.2 Data Related Referrals for Peripheral Neuropathy.....	5-5
	5.2.3 Definition of Sensate and Insensate for Referrals	5-6
	5.2.4 Data Related Referrals for ABPI.....	5-7
	5.3 Report of Findings for Peripheral Neuropathy	5-8
	5.4 Report of Findings for ABPI	5-10
6	QUALITY CONTROL.....	6-1
	6.1 Equipment and Room Set Up Checks.....	6-1
	6.1.1 Daily	6-1
	6.1.2 Weekly	6-3
	6.1.3 Stand.....	6-3
	6.2 Data Entry Screens for QC on Equipment and Room Set-up.....	6-4

TABLE OF CONTENTS (continued)

List of Appendixes

<u>Appendix</u>		<u>Page</u>
A	STANDARD SCRIPTS AND EXPLANATION OF EXAM PROCEDURES (ENGLISH AND SPANISH)	A-1
B	VIP SEQUENCE FOR LED EXAM.....	B-1
C	DATA ENTRY SCREENS.....	C-1
D	CALIBRATION ADJUSTMENT FOR THE PARKS MINI-LAB 3100.....	D-1

List of Tables

<u>Table</u>		
3-1	Arm circumference and acceptable cuff size	3-4

List of Figures

<u>Figure</u>		
2-1	Semmes-Weinstein monofilament	2-1
2-2	Parks Mini-Lab, Model 3100.....	2-2
2-3	Doppler probe	2-6
2-4	VIP pressure measurement screen	2-7
3-1	Classification of foot amputations	3-7
3-2	Bunion.....	3-8
3-3	Lesion (1).....	3-9
3-4	Lesion (2).....	3-9
3-5	Monofilament test.....	3-12
3-6	Location of the brachial pulse.....	3-17

TABLE OF CONTENTS (continued)

List of Figures (continued)

<u>Figure</u>		<u>Page</u>
3-7	Location of the posterior tibial pulses.....	3-18
3-8	Parks Mini-Lab vascular testing device.....	3-19
3-9	Position of Doppler probe.....	3-20
3-10	Pitting edema.....	3-26
3-11	Venous stasis.....	3-26
3-12	Black eschar.....	3-27
3-13	Callus.....	3-27
3-14	Fungal infected great toe.....	3-28

List of Exhibits

<u>Exhibit</u>		
4-1	Shared exclusion questions.....	4-1
4-2	Shared exclusion questions – amputation.....	4-2
4-3	Shared exclusion questions – weight limit.....	4-3
4-4	Shared exclusion questions – weight limit.....	4-4
4-5	Exam preparation – comments for arm.....	4-5
4-6	Exam preparation – required entry for comments.....	4-6
4-7	Exam preparation – arm cuff size.....	4-7
4-8	Exam preparation – large adult for arm cuff size.....	4-8
4-9	Poor thigh cuff fit.....	4-9
4-10	Arm cuff size – thigh.....	4-10

TABLE OF CONTENTS (continued)

List of Exhibits (continued)

<u>Exhibit</u>		<u>Page</u>
4-11	Exam preparation – change to right ankle	4-11
4-12	Exam preparation – could not obtain for ankles	4-12
4-13	Exam preparation – ankle cuff size.....	4-13
4-14	Abnormality observations – defaults	4-14
4-15	Abnormality observations – left foot amputation – drop-down menu	4-15
4-16	Amputation – left (entire foot).....	4-16
4-17	Amputation – left – could not obtain comments.....	4-17
4-18	Abnormality observations – left foot amputation – partial foot.....	4-17
4-19	Abnormality observations – left foot amputation – great toe	4-18
4-20	Abnormality observations – left foot amputation – other toes.....	4-19
4-21	Abnormality observations – left foot amputation – great toes and other toes .	4-20
4-22	Abnormality observations – left foot bunions – comments	4-21
4-23	Abnormality observations – left foot lesion – comment drop-down menu	4-21
4-24	Abnormality observations – left foot lesions – drop-down menu.....	4-22
4-25	Abnormality observations – left foot lesion ‘could not obtain’	4-22
4-26	Abnormality observations – right foot amputation – none	4-23
4-27	Peripheral neuropathy – left foot	4-24
4-28	Peripheral neuropathy – left foot – correct response, site 1.....	4-25
4-29	Peripheral neuropathy – left foot – correct response, site 2.....	4-26
4-30	Peripheral neuropathy – incorrect response message	4-27

TABLE OF CONTENTS (continued)

List of Exhibits (continued)

<u>Exhibit</u>		<u>Page</u>
4-31	Peripheral neuropathy – incorrect response on two sites	4-28
4-32	Peripheral neuropathy – incorrect responses on three sites	4-28
4-33	Peripheral neuropathy – incorrect responses same site.....	4-29
4-34	Peripheral neuropathy – 2 nd test, incorrect responses	4-29
4-35	Peripheral neuropathy – 3 rd test on a site	4-30
4-36	Peripheral neuropathy – normal sensation	4-30
4-37	Peripheral Neuropathy – decreased sensation.....	4-31
4-38	Peripheral neuropathy – unable to determine	4-32
4-39	Peripheral neuropathy – data entry (1).....	4-33
4-40	Peripheral neuropathy data entry (2).....	4-34
4-41	Peripheral neuropathy – right foot	4-35
4-42	Peripheral neuropathy – could not obtain	4-35
4-43	Peripheral neuropathy – callus.....	4-36
4-44	Peripheral neuropathy – lesions, bandages, elastic stockings	4-37
4-45	Peripheral neuropathy – amputation	4-38
4-46	Peripheral neuropathy could not obtain (3 sites)	4-38
4-47	Peripheral neuropathy – required response	4-39
4-48	Peripheral neuropathy – hallux amputation – left foot	4-40
4-49	Peripheral neuropathy – hallux amputation – right foot	4-40
4-50	Peripheral neuropathy – technical problems (1)	4-41

TABLE OF CONTENTS (continued)

List of Exhibits (continued)

<u>Exhibit</u>		<u>Page</u>
4-51	Peripheral neuropathy – technical problems (2)	4-42
4-52	Peripheral neuropathy – technical problems (3)	4-43
4-53	Peripheral neuropathy – technical problems (4)	4-44
4-54	Peripheral neuropathy – end of section.....	4-45
4-55	Peripheral neuropathy – Section 1 status screen	4-46
4-56	Status screen – Section 1	4-47
4-57	ABPI data capture – SPs aged 40 - 59	4-48
4-58	ABPI data capture – 60 years and above	4-49
4-59	ABPI data capture screen – right ankle pressure not captured.....	4-50
4-60	ABPI data capture – right ankle pressure not captured, PT pulse detected	4-51
4-61	ABPI data capture - right ankle pressure not captured, ankle pressure less than 255 mmHg	4-52
4-62	ABPI Section Status screen	4-53
4-63	LED exam status screen – Partial with comment required.	4-53
4-64	VIP choices menu (1)	4-54
4-65	VIP choices menu (2)	4-55
4-66	VIP ID entry screen	4-55
4-67	VIP choices menu (3)	4-56
4-68	VIP lower arterial test menu	4-56
4-69	VIP pressure measurement screen	4-57
4-70	VIP lower arterial test segmental limb pressures.....	4-58

TABLE OF CONTENTS (continued)

List of Exhibits (continued)

<u>Exhibit</u>		<u>Page</u>
4-71	VIP lower arterial test choices menu	4-58
4-72	VIP lower arterial choices menu	4-59
4-73	VIP lower arterial filer	4-59
4-74	VIP choices menu (3)	4-60
4-75	VIP choices menu	4-60
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 LED	5-3
5-4	Observation referral from LED in physician’s referral review box.....	5-4
5-5	Data related referrals for peripheral neuropathy	5-7
5-6	Data related referrals for ABPI	5-8
6-1	Quality Control reminder message box	6-4
6-2	Utilities menu to select Quality Control	6-4
6-3	User ID log on screen	6-5
6-4	Quality Control daily checks (1).....	6-5
6-5	Quality Control daily checks (2).....	6-6
6-6	Quality Control daily checks (3).....	6-6
6-7	Quality Control weekly checks.....	6-7
6-8	Quality Control start of stand checks.....	6-7
6-9	Quality Control incomplete entry	6-8

1. OVERVIEW OF LOWER EXTREMITY DISEASE

Lower extremity disease (LED) is a chronic, disabling disease that negatively influences the quality of life particularly in elderly and diabetic populations. The primary etiologic causes of LED are peripheral vascular disease (PVD) and peripheral neuropathy (PN) and in association with foot deformities may result in disabling complications such as ulcers, gangrene, and amputation. In the early stages of disease, a significant proportion of the population are asymptomatic but some of the identified risk factors include age, male sex, hypertension, hyperlipidemia, smoking, diabetes, and nutritional deficiencies. As the population ages, LED will become a major public health problem that will have an impact on health care costs and human suffering. Increasing the knowledge of the prevalence of LED and the associated risk factors may lead to early intervention and prevention of the disabling consequences of this disease.

1.1 Observation of Abnormalities

Foot abnormalities contribute to increased pressure over bony prominences and can lead to complication such as ulcers and amputations. Some common foot abnormalities include claw toes, hammer toes, prominent interphalangeal (IP) joints, hallux limitus, hallux valgus, bunions, calluses, and toe amputations. The assessment of foot abnormalities will permit the estimation of prevalence of those at high risk for disabling late-stage complications of LED and will provide information on risk factors for this disease.

1.2 Peripheral Neuropathy

Peripheral neuropathy (PN), characterized by numbness, reduction or loss of temperature and pain sensation, tingling, and muscle weakness and atrophy, is a common complication of diabetes. Some of the known risk factors include hyperglycemia, presence and duration of diabetes, male gender, and age. Reduced sensation can lead to a number of complications such as foot ulcers and amputation from undetected minor trauma.

A simple, noninvasive test to identify people who have lost protective sensation is monofilament testing, an evaluation of touch-pressure sensation, using a nylon monofilament to measure

cutaneous pressure sensation in the feet.^{1,2} An objective method to evaluate response to the Semmes-Weinstein pressure monofilament testing is a two-alternative forced choice algorithm (2-AFC).³ This method presents the examinee with a choice between an interval of stimulus from the monofilament and a second interval of background with no stimulus. Three metatarsal sites will be tested on each foot. The order in which the sites are tested and the interval in which the stimulus is applied will be randomly generated. The choice is to identify in which interval the stimulus occurred, not whether or not it occurred. Examinees who are unable to accurately identify the correct interval in which the stimulus was applied would be considered at risk for development of foot ulcers. The degree of loss of sensation will be used to categorize participants into categories of risk.

1.3 Peripheral Vascular Disease

Peripheral vascular disease is manifested by diminished blood flow to the legs and feet resulting in intermittent claudication (pain induced by walking and relieved by rest), chronic leg and foot ulcers, gangrene, and amputation. Arteriography is the gold standard for diagnosing PVD but the invasive nature of this test makes it unsuitable for epidemiologic studies.

The ankle brachial pressure index (ABPI), also referred to as the ankle arm blood pressure index (AAI), is a noninvasive technique to measure PVD in population-based and clinical studies.⁴ ABPI is defined as the ratio of the systolic blood pressure in the ankle compared with that in the arm, which provides a simple and reproducible measure of lower extremity arterial disease.

In the presence of medial arterial calcification, PVD may be underestimated by ABPI due to a high prevalence of medial arterial calcification in diabetics, people with neuropathy, and elderly men. Medial arterial calcification causes increased resistance of the vascular wall resulting in elevated ankle pressures, which affect the ABPI.

¹ Holewski JJ, Sress RM, Graf PM, Grunfeld C. Aesthesiometry: quantification of cutaneous pressure sensation in diabetic peripheral neuropathy. *J of Rehabilitation Research* 25:1-10, 1988.

² Sosenko JM, Kato M, Soto R, Bild DE. Comparison of quantitative sensory-threshold measures for their association with foot ulceration in diabetic patients. *Diabetes Care* 13(10): 1057-1061, 1990.

³ Sekuler R, Nash D, Armstrong R. Sensitive objective procedure for evaluating response to light touches. *Neurology* 23:1282-1291, 1973.

⁴ Orchard TJ, Standness DE. Assessment of peripheral vascular disease in diabetes: Report and recommendations of an international workshop sponsored by the American Heart Association and the American Diabetes Association, 18-20 September 1992, New Orleans, Louisiana. *Diabetes Care* 16:1199-1209, 1993.

1.4 LED in NHANES

Observation of abnormalities, monofilament testing, and ABPI measurement will be performed by a health technician on all adults 40 years of age and above at interview. Exclusions for these procedures are bilateral amputation, casts, ulcers, dressings, or other conditions which make BP readings at these sites impossible. The presence of these conditions on one limb will not exclude the SP. They will be excluded only if they occur bilaterally.

2. EQUIPMENT/SUPPLIES/MATERIALS

2.1 Description of Equipment

2.1.1 5.07/10 Gram Sensory Testing Monofilament

Monofilament testing is a simple, noninvasive test used to identify people who have lost protective sensation and who are at risk of developing ulcers. Touch-pressure sensation is evaluated by using a monofilament to measure cutaneous sensation in the feet.

The sensory testing device is a 5.07 Semmes-Weinstein nylon monofilament mounted on a holder that has been standardized to deliver a 10 gram filament force when properly applied. Research has shown that a patient who can feel the 10-gram filament in the selected sites is less likely to develop ulcers. The filament is applied perpendicular to the skin for a duration of 1½ seconds with enough force to cause the filament to bend.

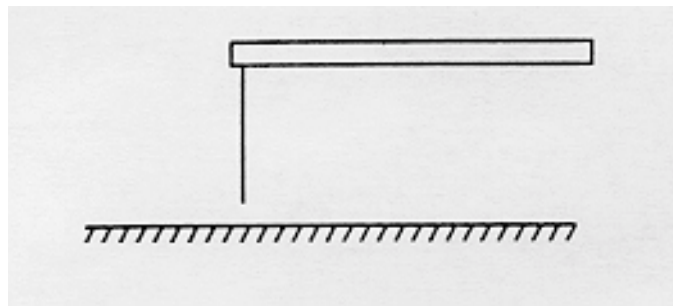


Figure 2-1. Semmes-Weinstein monofilament

2.1.2 Two Alternative Forced Choice (2-AFC) Algorithm

The 2-AFC is an interval comparison method to objectively assess cutaneous pressure sensation using Semmes-Weinstein monofilament testing. The monofilament is applied to each of three sites in random order at one of two distinct intervals. Random numbers will be generated by the Integrated Survey Information System (ISIS) to determine the order in which the sites are tested and the interval in which the stimulus is applied.

2.1.3 Parks Mini-Lab IV, Model 3100 (ABPI)

The Parks Mini-Lab IV, Model 3100 is a vascular testing device that can be used to measure systolic pressures in the extremities. The device will be integrated with ISIS and the measured data will be captured directly and downloaded into ISIS.



Figure 2-2. Parks Mini-Lab, Model 3100

Recorder Module

Power - The power indicator lights when this switch has been pressed. Pressing the switch again will turn off the power and indicator light.

Stop - This switch turns off the strip chart recorder. The strip chart recorder will not be used in this test.

5 mm/sec and 25 mm/sec - These switches start the strip chart recorder and control the speed of the recording. They have no effect on the speed of the monitor display. The strip chart recorder will not be used for these studies. A function key in the waveform mode screen (see VIP software) will control the speed of the monitor display.

Size - This controls the size of the waveform recorded on the waveform mode screen on the monitor (and also on the strip chart recorder). Turning the knob clockwise increases the size and turning the knob counterclockwise decreases the size.

Position - This control moves the trace baseline up or down on the strip chart recorder or the waveform mode screen on your monitor. Turning the knob clockwise moves the trace to the bottom on the waveform mode screen and turning the knob counterclockwise moves the trace towards the top.

Zero - Pressing this switch produces a zero reference line on the waveform mode screen on the monitor. This switch will not be used for these studies.

Doppler Module

Flow Direction - The light-emitting diode (LED) bar graph indicates whether the blood flow is toward or away from the probe.

Output Filter (Hz) - This knob selects the amount of filtering applied to the received Doppler signal. The switch is set to 28 for least filtering and Mean for the most filtering.

- The switch will be set to 3.5 for the ABPI measurements.

Volume - This knob controls the Doppler volume when the remote control is not plugged into the Mini-Lab. Turning the knob counterclockwise decreases the volume and turning the knob clockwise increases the volume. When the remote control is plugged in, the volume control knob is inactivated.

- The remote control will be used to control the volume for these tests.

Doppler Recording - This switch controls the direction in which forward and reverse flow components are displayed and recorded. Setting the switch to BOTH causes the forward component to be displayed as an upward deflection and reverse components as downward deflections.

- This switch will be set to BOTH for the ABPI measurements.

Doppler Probe - This switch selects which Doppler probe the Mini-Lab utilizes. The LO position uses a 4 MHz probe while the HI position uses an 8 MHz probe.

- The HI position for the 8.1 MHz Doppler probe will be used for the ABPI measurements.

Doppler Probe Installation - There are two frequencies on the instrument (high and low). Be sure the frequency on the panel matches the frequency on the probe plug. It is best to leave the probes connected rather than removing them frequently because repeated insertion and removal of the plugs wears out the connectors and ultimately causes static.

- To remove the probe, pull and twist the connector itself.
- Do not pull on the cable - the internal wires are very fragile and can break easily.

Mode Selector Module

Ready - This indicator lights when the Mini-Lab is ready to accept a signal input from either of the plethysmograph modes (VPR or PPG). It has no function when the Doppler is being used.

AC/DC/Reset - This toggle switch selects between the AC waveform operating mode and the DC waveform operating mode. The AC mode is used for recording arterial signals and the DC mode is for recording venous signals. Reset reestablishes the baseline when you are recording signals in the DC mode. Reset has no effect on Doppler signals.

- Only the AC mode will be used for these tests.

Sensitivity Hi/Lo - This toggle switch has two settings, HI and LO. Use the HI sensitivity position for recording digital waveforms. Use the LO setting for recording most VPR recordings.

- Only the LO setting will be used for these tests.

PPG/VPR/Doppler - This toggle switch selects between the three testing modes. The up position selects the PPG. Setting the switch to the middle position selects VPR and the bottom position selects Doppler.

- This switch will be set to the down position (DOP) for Doppler measurement of pressures for ABPI.

Remote Control/Cuff Inflator Module

Volume - This control is used to adjust the Doppler sound. The front panel volume control is active only when the remote is disconnected.

Inflate - In the Blood Pressure mode, the Mini-Lab inflates the cuff as long as the button is pressed or until 255 mmHg is obtained.

Bleed - In the Blood Pressure mode, pressing this button once slowly bleeds the air from the cuff. Pressing the button a second time stores the pressure in the Mini-Lab's memory and dumps the air from the cuff. The bleed rate is adjustable but a standard rate will be used for these tests.

- The standard deflation rate is set at 2 mmHg per second.

F9 - When the Mini-Lab is connected to a computer with the VIP program in a waveform mode, pressing this button once freezes the displayed trace on the waveform mode screen or captures the current blood pressure reading. Pressing the button again releases the waveform mode screen or the blood pressure reading.

F10 - When the Mini-Lab is connected to a computer with the VIP program in a waveform mode, pressing this button stores the blood pressure to the computer and Mini-Lab memory, deflates the cuff, and advances to the next segment. When not in waveform mode, pressing the F10 button stores the blood pressure in Mini-Lab memory, deflates the cuff, and advances to the next segment.

- The Mini-Lab will be connected to the ISIS system and the VIP software for these tests.

2.1.4 Dual Frequency Bi-directional Doppler

The Doppler probe consists of two crystals—one for transmitting the ultrasound waves and the other for receiving the reflected waves. If either crystal is damaged, the probe will not work properly or will not work at all. The crystals are covered by epoxy resin. Any gel or liquid containing the chloride ion attacks this resin. Therefore, ECG paste or cream must not be used as the contact medium between the skin and the crystals. Aquasonic or any gel made for ultrasonic physical therapy equipment can be used. If the probe has dried gel on it, it should be washed off under running water. Scraping the gel off may damage the epoxy coating. In order to get an audible signal that stands out well above the background noise, push the probe in toward the artery and angle the beam upstream and in line with the blood flow. There is a 3.9 MHz Doppler probe that is used for venous studies and an 8.1 MHz Doppler probe used for arterial studies. Only the 8.1 MHz Doppler probe will be used for these tests.



Figure 2-3. Doppler probe

2.1.5 Blood Pressure Cuffs

Blood pressure cuffs in four sizes (child - 9cm, adult - 12cm, large adult - 15cm, and thigh - 18cm) will be used for measurement of the pressure in the arms and ankles. All four sizes will be used on the arm. The child, adult, and large adult will be used on the ankle. An air hose will connect the cuff directly to the Parks Mini-Lab.

2.1.6 VIP Software

The Vascular Information Program (VIP) is a software program that will be integrated into ISIS and will be used to automate and standardize the vascular testing. There are two basic screen

formats: Text Mode Screen and Waveform Mode Screen. The Text Screen Format is used to make menu choices and enter data. The Waveform Mode Screen format is used to view and record waveforms. The latter has a timer on the top of the screen, a waveform grid in the middle, and relevant function keys on the bottom.

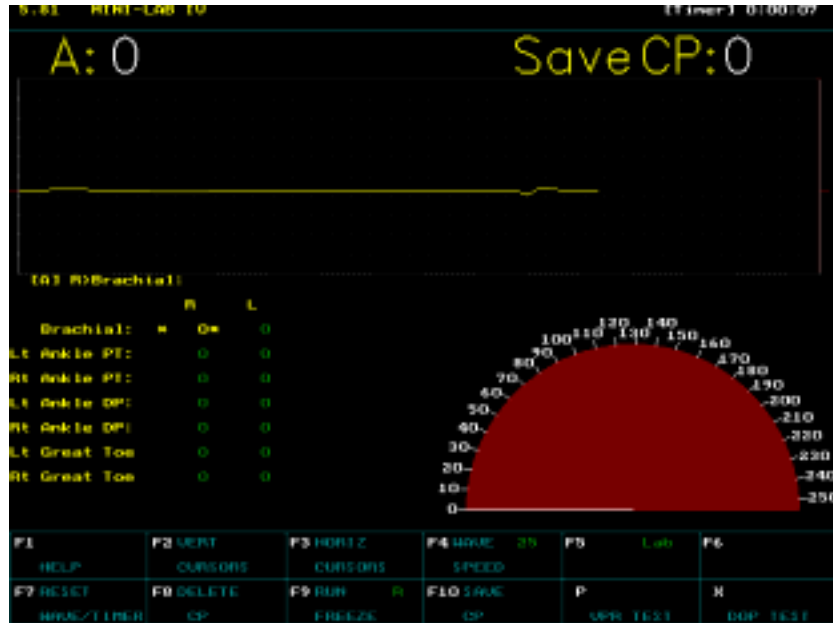


Figure 2-4. VIP pressure measurement screen

2.1.7 Mercury Manometer with Y-Connector for Calibration Check

A Baum calibrated mercury sphygmomanometer will be used for calibration check of the Parks Mini-Lab. The mercury-gravity manometer consists of a calibrated glass tube connected to a reservoir containing mercury. The mercury reservoir communicates with the pressure bulb through a Y-shaped rubber tube. When air pressure is exerted on the mercury in the reservoir by pumping the pressure bulb, the mercury in the glass tube rises to indicate the pressure in millimeters of mercury.

2.2 Maintenance of Equipment

2.2.1 5.07/10 Gram Sensory Testing Monofilament

The monofilament should be cleaned with alcohol and stored in its case after each use.

2.2.2 Parks Mini-Lab IV, Model 3100

Mini-Lab Testing Device - If the Mini-Lab is not operating properly, check the Operator's Manual and contact the MEC manager. If the problem cannot be resolved on site, contact the home office to arrange for repairs and replacement equipment.

Doppler Probe - *Do not use ECG paste or alcohol on the Doppler probe.* The active part of the probes consists of two crystals and they can be damaged by heat, alcohol, and ECG paste. Aquasonic gel only should be used with the Doppler. After use, wipe the gel off the end of the probe with a tissue. If gel has dried on the probe, do not try to scrape it off with a sharp instrument as this may damage the resin protecting the probe. Clean off the dried gel by placing it under cool (not hot) running water. A probe with a broken or cracked crystal must be replaced.

2.2.3 Mercury Sphygmomanometer (Used for Calibration Check)

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.

Weekly maintenance of manometer:

- 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. If the level of the mercury is above or below the zero line, there may be too much mercury in the reservoir, a mercury leak, or dirt in the mercury or in the calibrated glass tube. 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. If the shape of the mercury meniscus (top of the column of mercury) is not a smooth, well-defined curve, replace the equipment. This is also caused by dirt in the mercury or the glass tube.
- Check that the mercury rises easily in the tubing and that the mercury column does not bounce noticeably when the valve is closed. If the mercury does not rise easily in the tube, or if the mercury column bounces noticeably as the valve is closed, replace the equipment. The atmospheric pressure within the tube has been altered.
- 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 Y-connector, 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.
 - Connect the inflation system with a V-lok BP cuff and wrap it around a calibration cylinder.
 - 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 warehouse for repair or replacement.

2.3 Description of Supplies/Materials

- Doppler gel (Aquasonic). Do not use ECG paste.
- Alcohol wipes to clean monofilament.
- Large tissues to wipe gel from the skin and the Doppler.
- Latex gloves to be worn while performing this exam.
- Disposable pillows/disposable pillow covers
- Exam table paper
- Y-connector for calibration checks

2.4 Calibration Check on Parks Mini-Lab

The calibration of the Parks Mini-Lab will be checked each day with a mercury manometer. The reading on the Parks screen should be within +/- 5 mmHg from the reading on the mercury manometer. If the difference between the readings differ by more than 5 mmHg, the Mini-Lab will need to be recalibrated by the NCHS engineer or by US Instruments.

Daily Mini-Lab calibration check procedures are as outlined below:

Bring up the VIP application.

Type L for Lower Arterial, N for New Patient, Y to save current study.

Type QC (date) {Example: QC 03/28/99} in the name field. Press Esc.

Type T for Test Select, S for Segmental. Waveform Mode Screen is displayed.

Get calibration equipment: Portable mercury manometer

 Y-connector with rubber bulb

Set up portable mercury manometer on right side of Parks.

Check that the meniscus on the mercury manometer is reading zero. The reading on the mercury manometer should always be done with your eye level at the meniscus.

- If meniscus is not at zero, turn the mercury manometer 'slowly' on its side (right side) and then back to the original position. The meniscus should be at zero.
- If the meniscus is not at zero, report this to the Chief Technician. The manometer should be returned to the manufacturer for re-calibration.

Connect male connector from mercury manometer to female connector on Y-tubing.

Disconnect Parks air hose from monitor.

Connect gold colored adapter on Y-tubing to 'BP/occluding Cuff ' outlet on Parks monitor.

Use the following steps to check the calibration of the Parks Mini-lab with the mercury manometer. The calibration will be checked at these ranges:

- 220 – 250
- 180 – 220
- 120 - 180
- 70 – 120
- 0 –70

Close the screw on the rubber bulb (turn the screw clockwise).

Using the rubber bulb, slowly inflate the mercury manometer to 220 –250. Check the reading at eye level. **(Do not use the Parks remote to inflate – use the rubber bulb only.)**

Note the number next to ‘A:’ at the top left corner of the screen on the Parks VIP screen.

The number on the Parks monitor should be within +/- 5 of the reading at eye level on the mercury manometer.

Slowly deflate the manometer to a number in the next range.

Repeat this for a number in each of the ranges listed above.

Put a check in the box on the QC screen to indicate that the calibration was checked.

If the difference between the Parks monitor and the mercury monitor is +/-5:

If the number is within +/-5, enter a check beside this item on the Quality Control Screen. See Figures 6.7 and 6.8.

If the number deviates by more than +/-5:

- Check that all connections with the Y-connector, manometer, and monitor are tight.
- With the Y-tube completely deflated, check that the reading on the mercury manometer is at zero. Repeat the calibration if necessary.

Enter the difference between the readings in the 'Result' section of the Quality Control screen. See Figure 6.8.

Enter the reading noted on the mercury manometer and the reading noted on the Parks VIP screen in the 'Comments' field of the Quality Control screen. See Figure 6.8.

Report the difference to the Chief Technician and MEC manager.

The Parks Mini-Lab will either be recalibrated by the NCHS Biomedical Engineer or sent to US Instruments for recalibration. Procedures for recalibration are written in Appendix D and in the Parks Bioengineering Manual that is kept in the LED Room on each MEC.

2.4 Mercury Spills or 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 follow-up 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.

- a. Leakage or spillage on a hard surface (e.g., hard floor, table, etc.)
 - Get the Mercury Spill Kit from the physician's exam 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.
 - Complete a Mercury Spill Report Form.
 - Obtain replacement equipment.
- b. Leakage and/or spillage on a soft or absorbent surface (e.g., rug, clothing, etc.):
 - Get the Mercury Spill Kit from the physician's exam 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.
- Complete a Mercury Spill Report Form.
- Obtain replacement equipment.

3. PROTOCOL

3.1 Overview of LED Exam

The Lower Extremity Disease ISIS application is divided into two sections. Section One is composed of the cuff selection and application process, the observation of abnormalities, and the peripheral neuropathy exam. Section Two is the Ankle/Brachial Pressure Index. See Chapter 4 for an in-depth description of the data entry screens for both sections.

3.2 Introduction to Exam

The examiner should briefly explain the exam when the SP is brought into the room. The exam should be explained in more detail as each section is being performed. The objective is to inform the SP about the exam and to position the SP for the exam as quickly as possible. Below is a suggested introductory script but the examiner may use his/her own words for this explanation. This is not a standard script.

Suggested Introduction to Component (Not a Standard Script) English Version

In this room I am going to do several tests to measure the pressures in your arm and ankles. I'll explain the test in more detail as we go through the test. First I am going to check the circumference of your arm in order to fit you with the correct blood pressure cuff. After I obtain the correct cuff size, I will ask you to lie down on the table and get as comfortable as possible, and I will put blood pressure cuffs on your arms and ankles. The purpose of this set of tests is to give us some information about peripheral vascular disease or disease that affects the blood vessels in the lower legs and ankles.

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

“En este cuarto voy a hacer varias pruebas para medirle la presión de los brazos y de los tobillos. Le explicaré la prueba con más detalle mientras hacemos la prueba. Primero voy a verificar la circunferencia de su brazo para poder escoger la banda correcta que mide la presión sanguínea. Después de que obtenga el tamaño correcto de la banda, le pediré que se acueste sobre la mesa y se ponga lo más cómodo(a) posible, y le pondré las bandas para medirle la presión sanguínea en los brazos y en los

tobillos. El propósito de este conjunto de pruebas es obtener alguna información acerca de cualquier enfermedad vascular periférica o enfermedad que afecte los vasos sanguíneos en la parte inferior de las piernas y en los tobillos. Esta enfermedad se produce en algunas personas cuando envejecen, particularmente en los diabéticos.”

3.3 Safety/Exclusion Criteria

- The safety/exclusion questions on the first screen are standard questions, not observations. If these two questions have not been asked in a previous component (completed and grayed out on the screen), you must read the question to the SP word for word and record the response. Although the responses may be obvious, they are not observations and in the interest of standardization across components, you must treat them as questions, not observations.
- Blood pressure will be measured on the right arm for the ABPI section of the exam. If phlebotomy has been performed on the right arm, the phlebotomist will place a transparent film over the puncture site. The systolic brachial measurement may be taken over this transparent film. If there is oozing at the puncture site, do not take the measurement on this arm. Use the left arm for the brachial measurement. The skin of the elderly can be very thin and fragile and the transparent dressing may irritate or cause the skin to tear when the dressing is removed. The phlebotomist will use judgment when applying the transparent film dressing to the elderly. If the phlebotomy site is covered by a regular Band-Aid or CoFlex, do not use this arm. Use the left arm for the brachial measurement.
- If the SP has a rash or open wound on the right arm, dialysis shunt, right-sided radical mastectomy, or any other condition that would interfere with accurate measurement or would cause discomfort to the SP, the left arm will be used for the brachial pressure measurement.
- If the SP has a rash or open wound on both arms that would interfere with accurate measurement or would cause discomfort to the SP, the SP will be excluded from the ABPI section of this exam. Continue with observation for abnormalities and monofilament testing.
- If the SP has venous stasis ulceration or other pathology that precludes placing a blood pressure cuff around the right OR left ankle (e.g., open wounds, small gauze/adhesive dressings, casts, puffiness), measurements will not be made on the affected ankle. Measurements can be made on the unaffected ankle.
- SPs with venous stasis ulceration or other pathology that precludes placing a blood pressure cuff around BOTH ankles (e.g., open wounds, small gauze/adhesive dressings, casts, and puffiness) will be excluded from the ABPI measurements. Continue with observation for abnormalities and monofilament testing.
- SPs with bilateral amputations of legs will be excluded from the entire exam. This question is one of the Shared Exclusion Questions that will normally be asked in the Household Exam. See Section 4.1 for a more detailed explanation.

- The weight limit restriction on the stretcher used for the exam is 400 pounds. A SP with a MEC-recorded weight of less than 400 pounds is eligible for the exam. SPs with self-reported weight of 350 pounds or greater should have their weight confirmed on the MEC before getting on the LED stretcher. See Section 4.1 for more details.

3.4 Cuff Selection for ABPI

It is important to select an appropriate size blood pressure cuff that properly fits the arm of the SP. According to the American Heart Association, the length and width of the bladder inside the cuff should encircle at least 80 percent and 40 percent of an adult's arm, respectively. The appropriate cuff to be used is determined by the circumference of the arm. The arm circumference will be obtained as outlined below:

- With the SP standing, determine the midpoint of the upper arm by measuring the length of the arm between the acromium and olecranon process (between the shoulder and elbow) with the metal centimeter tape. The arm must be bent, with the palm facing upwards.
- Mark the midpoint of this measurement with a cosmetic pencil.
- Ask the SP to relax the arm and lower the palm. Measure the circumference of the bare upper arm at the midpoint. The zero end of the measuring tape must be at the bottom of the two ends of the tape. Make sure that the tape is snug against the arm and there are no pinched folds of skin.
- Find the arm circumference under column 4 in Table 3-1 (adapted from Human Blood Pressure Determination by Sphygmomanometry by the American Heart Association).
- Use the cuff size from column 1 associated with the arm circumference in column 4. (Example: If the arm circumference at midpoint is 32 cm, use the large adult cuff.)

Table 3-1. Arm circumference and acceptable cuff size

Cuff Size	Bladder width (cm)	Bladder length (cm)	Arm circumference (cm)
Child/small adult	9	17	17-21.9
Adult	12	22	22-29.9
Large adult	15	32	30-37.9
Adult thigh	18	35	38-47.9

The arm must be measured at the beginning of the exam before the SP is positioned on the stretcher. However, if the SP has already had his or her arm measured in the Anthropometry component, the arm circumference should be written on the SP's shirt. It is not necessary to measure the arm a second time; the technician can use the arm circumference obtained in Anthropometry. In addition, if the SP has seen the physician before coming to LED, the physician will have written the cuff size on the SP's shirt. The technician should use the cuff size obtained by the physician.

NOTE: For SPs with very large but short arms that fall into the thigh cuff range, it may be necessary to downsize to the large adult cuff. If the thigh cuff covers the antecubital space and interferes with placement of the Doppler probe, the technician should switch to the large adult cuff and note the reason for the change in ISIS. It is not always possible to obtain a perfect cuff fit and you should always do the best you can to adjust the cuff fit. Although on occasion it may be necessary, 'Poor cuff fit' should not have to be used frequently as a reason for not obtaining the blood pressure measurements.

3.5 Positioning for the LED Exam

The SP will be positioned supine on the exam table for the entire LED exam. He or she will be asked to lie down on the stretcher after the cuff size has been determined and preparations for the exams will begin. Some SPs may have difficulty taking off and putting on their socks for this exam. Always ask if the SP needs help with this especially with the older SPs. A convenient way to do this is to get the SP to lie down on the table, take off the socks and leave them on the side of the table. After the exam is finished, the socks are close by so you can put them back on while the SP is still lying down. Although observation for abnormalities and monofilament testing will be done prior to the measurement of the pressures, the arm and ankle cuffs will be applied first to allow a brief resting period and optimize stabilization of blood pressure prior to measurement. If the SP is uncomfortable lying flat, the head of the bed may be raised slightly.

- Examiners are required to wear gloves for this exam. Prior to putting on the blood pressure cuffs, the examiner should put on gloves.
- The examiner should have access to the right arm and both ankles. (If the right arm cannot be tested for some reason, use the left arm).
- Both feet and ankles should be bare to the mid-calf.
- The sleeve of the arm should be rolled up so the upper arm is bare.

3.5.1 Brachial Cuff

- Palpate the brachial artery on the inner aspect of the upper arm (not the antecubital space).
- Place the center of the bladder (marked on the cuff with a line and circle) over the palpated artery. The circle marking the center of the bladder should be on the inside of the upper arm.
- Wrap the cuff smoothly and snugly around the arm. Cuff should be wrapped in a circular manner. No spiral direction of the cuff should be used. (This does not apply for application of the ankle cuffs).
- Check the fit by placing both thumbs under the cuff and tugging gently. Should the cuff slip or come off, reposition and rewrap the cuff securely.
- Connect the cuff to the air hose before taking the pressure.

3.5.2 Ankle Cuffs

- Palpate a posterior tibial artery on the ankle next to the medial malleolus.
- Place the center of the bladder (marked on the cuff with a line and circle) over the palpated artery and above the medial malleolus. It is important to allow enough space above the malleolus to have adequate access to the pulse site.
- Place one cuff on each ankle.
- The cuffs may have to be spiraled slightly to fit the ankle.
- Connect the cuffs to the air hose before measuring the pressure.

3.6 Observation for Abnormalities

Both feet will be assessed for the presence or absence of amputations, bunions, and lesions. These abnormalities are described below. Do not remove bandages or compression stockings. If bandages or stockings prevent observation of the feet, enter 'could not obtain' and select the appropriate comment.

You should examine the planter surface of the foot with your hands for the presence of calluses when assessing the foot for abnormalities. Calluses are not always visible to the eye and you want to confirm that the site to be tested for peripheral neuropathy is free of calluses. Although calluses are not recorded as a data point for NHANES, the presence of very large and thick calluses may interfere with peripheral neuropathy testing. If a callus is present, the technician should lightly touch the plantar surface of the foot in the metatarsal area to determine the thickness and spread of the callus. If the callus covers the entire metatarsal area, or the entire top half of the foot, monofilament testing cannot be done on that site. The technician will note the callus by marking 'could not obtain' with reason 'callus' for that site.

- Observe both feet for each of the abnormalities described below.
- For each abnormality, record if present, absent, or could not obtain.

Amputation - (See Figure 3-1)

- **None** - The system will set the default to none. If there are no amputations, the system will set Bunions and Lesions to No as the default.
- **Entire Foot** - Amputation at the ankle or above. This includes any amputation that is higher than a transmetatarsal or partial foot amputation.
- **Partial Foot** - (Transmetatarsal) Amputation of the great toe and all of the other toes.
- **Great Toe** - Amputation of the great toe only.
- **Other Toe(s)** - Amputation of one to four of the other toes. This does not include the great toe.
- **Great Toe and Other Toe(s)** - Amputation of the great toe and one to three of the other toes. If all four of the other toes are missing, this would be defined as a partial foot.

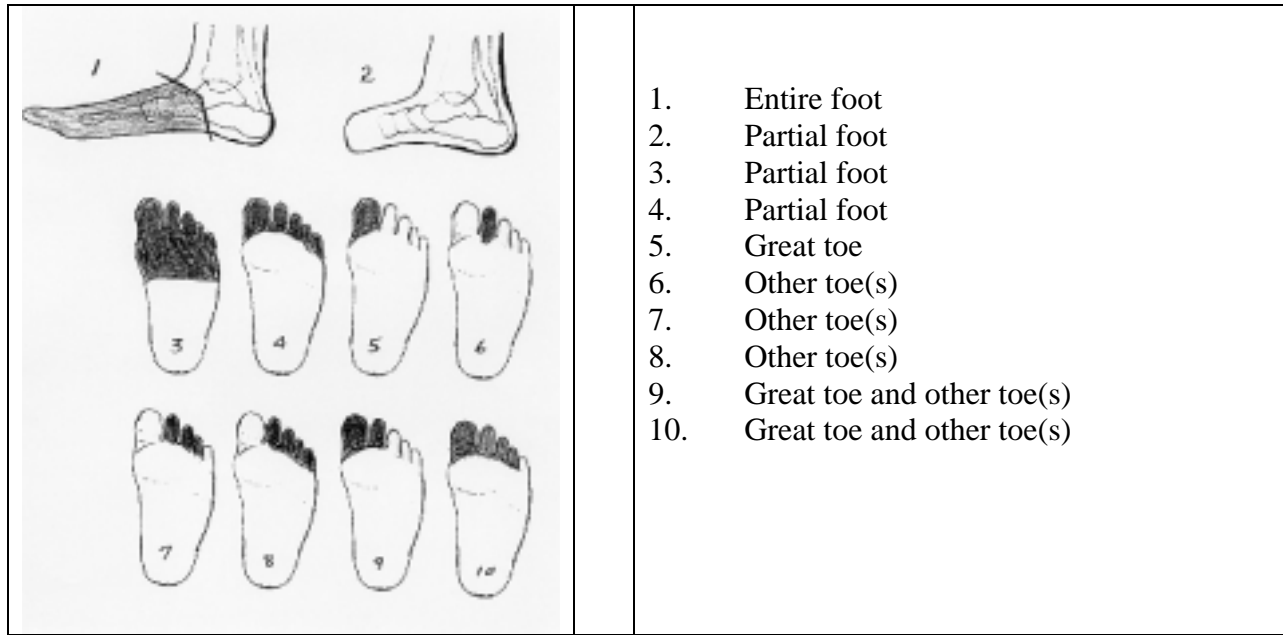


Figure 3-1. Classification of foot amputations

Bunions - Abnormal prominence of the inner aspect of the first metatarsal head, accompanied by bursal formation and resulting in a lateral or valgus displacement of the great toe. See Figure 3-2.



Figure 3-2. Bunion

Lesions - Lesions may develop at pressure points on the feet especially when pain sensation is diminished or absent (as in neurotrophic ulcers in people with diabetic neuropathy).

For this survey, lesions are defined as bandages, blisters, ulcers, abrasions, lacerations, and sutures. Fissures between the toes will not be defined as lesions. Bandages or pressure stockings covering all or part of the foot will not be removed for this assessment even if the SP volunteers to remove them. The same is true for elastic or pressure stockings. Figures 3.3 and 3.4 are examples of types of lesions that may be seen of the foot.



Figure 3-3. Lesion (1)



Figure 3-4. Lesion (2)

3.7 Monofilament Testing

3.7.1 Explanation of the Test

The following explanation and demonstration should be done prior to the monofilament test. This is a standard script and the same directions must be used each time. Technicians must carefully explain and demonstrate the monofilament test, and ascertain if the SP has understood the instructions before beginning the test. Some SPs may not be able to understand the instructions for the monofilament test because of a language barrier or a learning deficit, for example. If it becomes apparent during the explanation and demonstration that a SP cannot, for any reason, follow the instructions for the monofilament test, the technician should not perform the peripheral neuropathy section of the exam. The technician can end that section of the exam and go directly to the ankle-brachial pressure index section. Examples of the data entry screens for the end of Section One are in Section 4.4.3 of this manual.

Standard Script (English Version). “Before I take the pressures, I want to test the sensation or sense of touch on the bottom of your feet. To do this test, I will use this small filament to apply pressure to different spots on your foot. It is not sharp and will not break the skin.”

(Technician will show the SP the filament and touch the SP’s arm with the filament so the SP will know what to expect).

“As I apply the pressure I will be saying ‘A, B’ and I will be applying the pressure either as I am saying ‘A’ or as I am saying ‘B’. I want you to tell me whether you felt the pressure when I said ‘A’ or when I said ‘B’. Let me demonstrate on your arm.”

(Demonstrate the procedure on the SP’s arm. Be sure the SP understands the test before starting. Repeat the explanation if necessary).

“Do you understand?”

Standard Script (Spanish Version).

Explanation of Peripheral Neuropathy. “Antes de que le tome las presiones, quiero hacerle una prueba de la sensación o sentido del tacto en la planta de los pies. Para hacerle esta prueba, usaré este pequeño filamento para aplicar presión en diferentes puntos del pie. No es punzante y no le romperá la piel.”

(Technician will show the SP the filament and touch the SP’s arm with the filament so the SP will know what to expect).

“Mientras aplico la presión diré ‘A, B’ y aplicaré la presión ya sea cuando esté diciendo ‘A’ o cuando esté diciendo ‘B’. Quiero que usted me diga si sintió la presión cuando yo dije ‘A’ o cuando dije ‘B. Déjeme hacerle una demostración en el brazo.”

(Demonstrate the procedure on the SP’s arm. Be sure the SP understands the test before starting. Repeat the explanation if necessary).

“¿Comprende?”

3.7.2 Sites to be Tested

- Site # 1 Plantar - first metatarsal head.
- Site # 2 Plantar - fifth metatarsal head.
- Site #3 Plantar – hallux.

3.7.3 Order for Testing Sites

The sites will be tested in a nonsequential order to allow for better discrimination of sensation by the examinee. Random numbers will be generated by ISIS to determine the interval in which the stimulus is applied.

- ISIS will display the diagram of the foot with the site and interval selection.
- The examinee should not be able to see which site is being tested.
- The site to be tested will be highlighted on the screen.

3.7.4 Standard Procedures

- The SP will remain in the supine position, resting quietly.
- The examiner should wear latex gloves.
- Both feet will be tested. ISIS will prompt the examiner to begin with the left foot.
- Use the 0.5/10 gram filament to test sensation.
- Follow the order on the computer screen for the sites to be tested.
- Check the screen for the interval in which to apply the stimulus.
- Test the first site selected by ISIS.
 - Explain the procedure to the participant using the standard script. Demonstrate applying the filament on his/her hand.
 - Note the interval to apply the stimulus (Interval A or Interval B).
 - When applying the filament say out loud, “A, B.”
 - Do not change the inflection in your voice with the interval change.
 - Apply the filament to the skin’s surface at either Interval A or Interval B as determined randomly by ISIS.

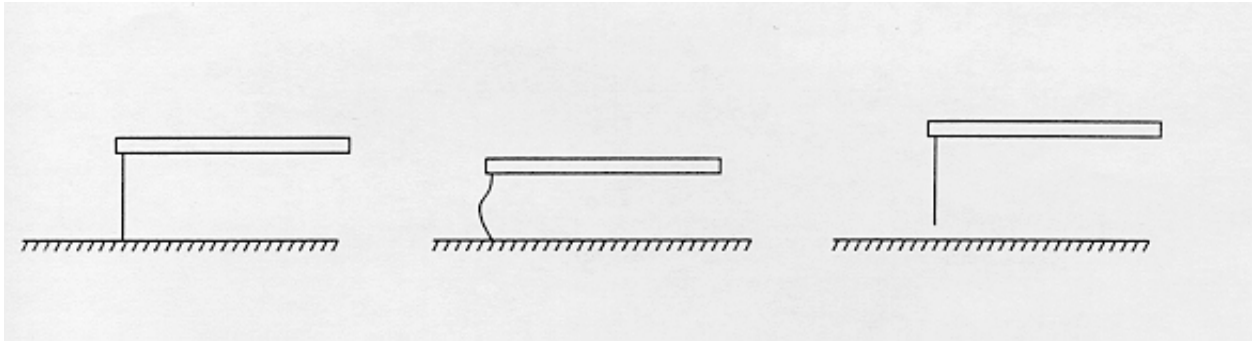


Figure 3-5. Monofilament test

- Apply the filament perpendicular to the skin's surface.
- The approach, skin contact, and departure of the filament should be approximately 1 1/2 seconds duration.
- The examinee can choose one of three options:
 1. Interval A;
 2. Interval B; or
 3. Unable to determine the interval with the stimulus.
- Record the response as one of the following options:
 1. Correct;
 2. Incorrect;
 3. Unable to determine; or
 4. Could Not Obtain.

3.7.5 Definition of Responses

Correct. Should be selected when the SP correctly selects the interval in which the stimulus was applied.

- If a correct response is selected for the first test, that site does not have to be tested again.
- The system will leave the second and third test for that site disabled and will highlight the next site to be tested.

- If an incorrect or unable to determine response is obtained for the first test and a correct response is obtained for the second test on the same site, the test will have to be repeated a third time to get two similar responses.

Incorrect. Should be selected when the SP does not correctly select the interval in which the stimulus was applied. For example, if the technician applies the stimulus on interval A and the SP selects B, the technician should enter ‘Incorrect’ in ISIS.

- An incorrect response could indicate decreased sensation to that site or a problem with SP concentration.
- If incorrect is selected for a site, the system will display a message that the site must be re-tested up to three times. You must have two similar responses to each site to determine if that site is sensate or insensate. The system will enable the second and/or third test fields for that site. This allows confirmation of an incorrect response.
- The next site to be tested in sequence will be highlighted. All three sites are tested once before the second and third test for any site is tested.
- The SP could give an incorrect response if the filament is applied incorrectly. ‘Incorrect’ should not be selected if the filament was not applied correctly. If an incorrect response is obtained because the filament was not applied correctly, the technician should select ‘Could Not Obtain’ with the comment ‘technical problem’. See ‘Could Not Obtain’ below.

Unable to Determine. Should be selected when the SP is unable to determine whether the stimulus was applied during Interval ‘A’ or ‘B.’ For example, if the technician applies the stimulus on interval A and the SP says “Both,” “I don’t know,” “Neither,” or any other response that indicates the SP is unable to select an interval, the technician should enter ‘Unable to Determine’ in ISIS.

- An unable to determine response could indicate decreased sensation to that site or a problem with SP concentration.
- If unable to determine is selected for a site, the system will display a message that the site must be re-tested up to three times. You must have two similar responses to each site to determine if that site is sensate or insensate. The system will enable the second and third test fields for that site. This allows confirmation of an unable to determine response.
- Both incorrect and unable to determine responses may indicate decreased cutaneous sensation to that site. In addition, it is possible that the SP may not have understood the explanation or has lost concentration briefly during the exam. On some occasions a SP may say that he is not sure, doesn’t know or he/she may ask to have the test repeated. In these situations, the technician should enter the first response given for that site and move on to the next site.
- The SP could give an unable to determine response if the filament is applied incorrectly. ‘Unable to Determine’ should not be selected if the filament was not

applied correctly. If an unable to determine response is obtained because the filament was not applied correctly, the technician should select 'Could Not Obtain' with the comment 'technical problem'. See 'Could Not Obtain' below.

Could not Obtain. Should be selected when the site to be tested cannot be tested for whatever reason. The most likely reasons would be a bandage, elastic stocking, callus, cast, or something else covering the site. Do not remove bandages, casts, or pressure stockings to do this exam. Another reason for a 'Could Not Obtain' response is amputation.

- Select 'Could Not Obtain' and select the appropriate comment from the 'Comment' drop-down menu.
- If 'Could Not Obtain' is selected for the first test, it is impossible to have a different response for a second or third test under most circumstances. If you are unable to test a site due to a bandage or lesion for test 1, there should not be a different response for Test 2. If 'Could Not Obtain' is selected with every comment except 'technical problem', the system will disable Test 2 and 3 for that site. *There is no second or third test field for 'Could Not Obtain' except for one exception. See Could Not Obtain - Technical Problem below.*

Could not Obtain (Technical Problem). Should be elected if the monofilament is applied incorrectly. There are several problems that may occur when performing the monofilament test. These problems have the potential of giving invalid results for the test. These problems are:

- The monofilament is not applied with the standard amount of force.
- The monofilament may slip off the site being tested.
- The pressure may have been applied on the wrong interval.
- The pressure may have been applied on both intervals.

3.7.6 **Completing the Monofilament Test**

- Record the results of each site as it is tested.
- Repeat the entire procedure for the right foot.
- After the exam is completed, clean the monofilament and replace in the case.

Review of Responses for Monofilament Testing

- If SP correctly identifies the interval in which the stimulus was applied: **Correct.**

- If SP correctly identifies the interval in which stimulus was applied but the technician inadvertently administered the test incorrectly: **Could Not Obtain (comment - technical problem)**.
- If the SP incorrectly identifies the interval in which the stimulus was applied (e.g., the technician applied the stimulus on “A,” but the SP said “B”): **Incorrect**.
- If the SP incorrectly identifies the interval in which the stimulus was applied but the technician inadvertently administered the test incorrectly: **Could Not Obtain (comment -technical problem)**.
- If the SP is unable to determine in which interval the stimulus was applied and responds with ‘I don’t know,’ ‘I’m not sure,’ ‘Could you repeat the test?’ or a similar comment: **Unable to Determine**.
- If the SP is unable to determine in which interval the stimulus was applied and responds with ‘I don’t know,’ ‘I’m not sure,’ ‘Could you repeat the test?’ or a similar comment but the technician inadvertently administered the test incorrectly: **Could Not Obtain (comment -technical problem)**.
- If there is an amputation or lesion at the site: **Could not Obtain**.
- If the site is covered by a bandage, cast, elastic stocking or other covering: **Could not Obtain**.

3.8 Ankle Brachial Pressure Index (ABPI)

3.8.1 Explanation of the ABPI and Doppler

Suggested Explanation of ABPI and Doppler (Not a Standard Script) English Version

“I will be using this instrument called a Doppler to measure your blood pressures, rather than a stethoscope that is usually used to take blood pressure in a physician’s office.

I will be wearing headphones to hear the Doppler sounds and to block out any extra noises. Do you have any questions before I begin?”

Suggested Explanation of ABPI and Doppler (Not a Standard Script) Spanish Version

“Voy a usar este instrumento, que se llama “Doppler,” para medir su presión sanguínea en vez de un estetoscopio que normalmente se usa en un consultorio médico para medir la presión sanguínea.

Voy a usar audífonos para oír los sonidos del “Doppler” y para no oír otros sonidos. ¿Tiene usted alguna pregunta antes de empezar?”

3.9 Locating the Doppler Pulse Sites

- In order to accurately place the Doppler probe on a site, the brachial and posterior tibial (PT) pulses should first be located by palpation. Palpation of the pulses gives you important information about the pulse volume, location, and direction of flow. Don't spend more than 20-30 seconds trying to palpate the pulses if you are having difficulty. If you cannot palpate the pulse, you may still be able to locate it with the Doppler. Locating each of these pulses is described below.

Brachial Pulse

- Position the SP's arm with the palm turned up with the arm straightened and slightly bent at the elbow.
- With the first two fingers of your hand on the innermost part of the crease of the elbow, palpate for the brachial pulse. (See Figure 3-6.) NOTE: The pulse used for the Doppler probe is different than the pulse used for placement of the blood pressure cuff.
- If the pulse is not felt, move your fingers slightly closer to the center of the arm and check for the pulse at this site.

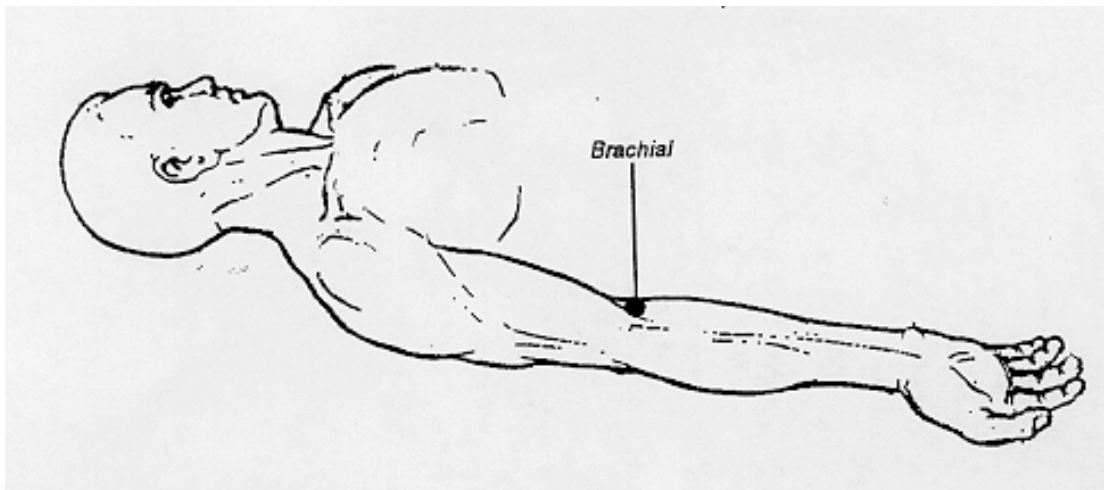


Figure 3-6. Location of the brachial pulse

Posterior Tibial Pulses

- Curve your fingers behind and slightly below the medial malleolus of the ankle. (See Figure 3-7).

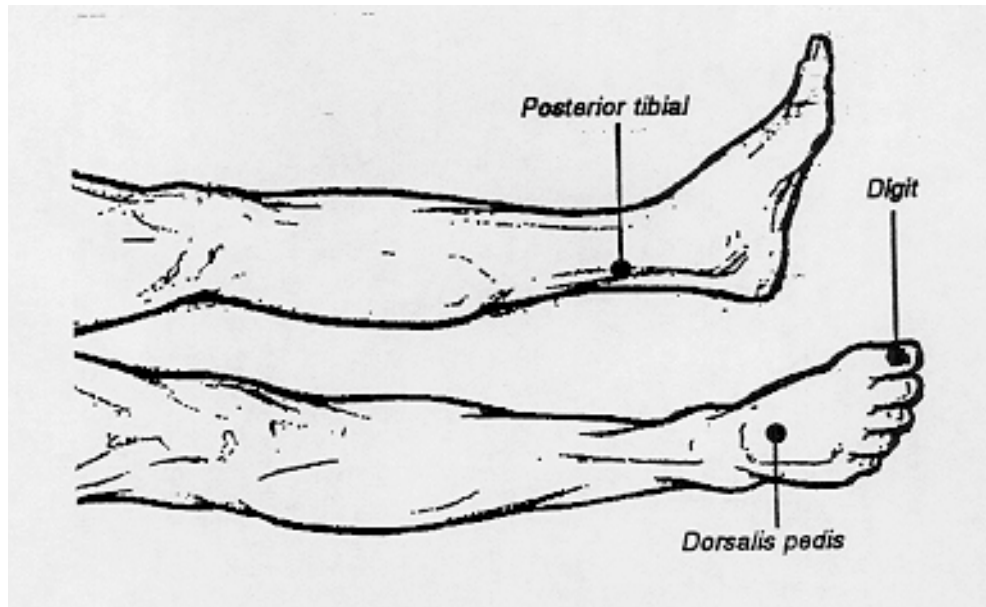


Figure 3-7. Location of the posterior tibial pulses

3.10 Preparing the Equipment for Measurement

3.10.1 Preparing the Vascular Testing Device

- Check that the Power indicator is “On.”
- Check that output filter is set to 3.5.
- Check that AC/DC/Reset switch is set to AC.
- Check that Sensitivity is set to Lo.
- Check that PPG/VPR/Doppler switch is set to Doppler.
- Confirm the 8.1 Doppler is connected to the correct port.
- Confirm Aquasonic Gel is available.
- Confirm air hose is attached to Parks monitor.
- Confirm Remote Control is connected to the module.

- Confirm volume on Remote Control is turned down.
- Confirm headphones are connected to Parks Mini-Lab at the headphone port.



Figure 3-8. Parks Mini-Lab vascular testing device

3.10.2 Preparing the VIP Software

At Main Menu:

- L - for Lower Arterial;
- N - for New Patient;
- Y - for “Do you want to save the current study?”;
- Enter SP ID;
- Press Escape;
- T - for Test Select; and
- S - for Segmental Limb Pressures.

Waveform Mode appears.

Software is ready to begin test. Instruct examinee to try to relax as much as possible prior to pressure readings.

3.11 Doppler Measurement of Pressures

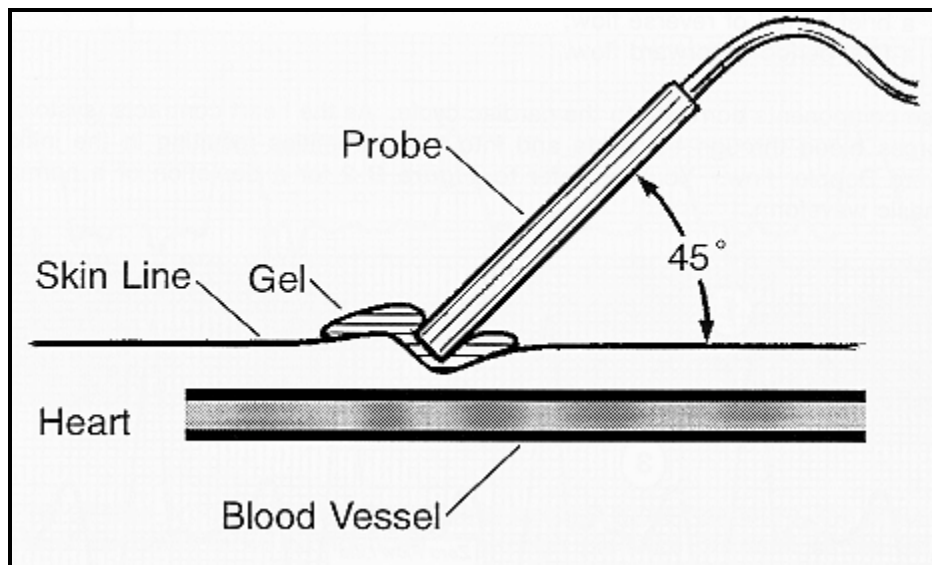


Figure 3-9. Position of Doppler probe

- An 8 MHz Doppler probe will be used to determine the systolic pressure at each of the sites. The position of the Doppler probe is very important for accurate measurement.
- Headphones will be used for this portion of the LED exam in order to eliminate the noise generated from the Doppler probe. Technicians must put on the headphones before searching for a pulse with the Doppler probe. Once the headphones are in place, the volume can be adjusted to any level in order to find the best quality signal and maintain technician comfort.
- Put about a quarter of an inch of gel on the tip of the probe or on the skin.
- Ultrasound needs a continuous conducting medium such as the gel so check that there are no large air bubbles in the gel.
- Place the probe over the artery and tilt the probe back to approximately a 45-degree angle to the artery. (The ideal angle would be to have the probe pointing down the lumen of the artery but this is not possible.)
- Try to keep the probe at a 45 - 60 degree angle to the skin over the artery.

- The probe must be pointing toward the head (cephalad).
- Search for the best quality signal.
- Stabilize your hand and arm prior to initiating the measurement to ensure that you are able to hold the Doppler in position as the cuff inflates and deflates.

3.12 Sequence of Taking Systolic Measurements

The sequence for taking the systolic pressure measurements is:

- Right Brachial
- Left Ankle PT
- Right Ankle PT

Second set of measures (40-59 years only)

- Left Ankle PT
- Right Ankle PT
- Right Brachial

3.13 Deleting Data

There may be instances when a blood pressure is not obtained at one of the sites due to movement of the Doppler probe during cuff inflation, a faint pulse that does not correspond to a waveform on the VIP screen, or other technical or SP dependent errors. Rather than guess if a blood pressure is correct, the technician should delete the questionable value (press F8 if the number was saved) and move on to the next site. When a value is not obtained at a site, the technician must remember to move the cursor on the VIP screen to the next site using the arrow keys on the keyboard.

3.14 Repeating Missed Measures

The technician should always stay in the exam sequence outlined in section 3.12, and can return to any site after blood pressures are captured in other sequential sites. Each site can be tried up to three times for all SPs regardless of age. A blood pressure should not be attempted twice in a row at the

same site without a minute rest in between attempts. The purpose of allowing a rest period is for SP comfort, and to avoid any effect measurement might have on the reading. In the interest of time, technicians should move to the next site in a sequence of ABPI measures, rather than waiting one minute with no activity. If the pressure that is missed is the last in a sequence, a technician may wait one minute and try again. When setting the cursor for the measurements, you should always move the cursor back to the place for the first measurement until you have captured a pressure in that field. The first measurement is the first pressure you obtained, not attempted.

If a SP is 60 years old or older, note that ISIS will only capture data from the slots with a (1) next to them on the VIP screen. The cursor on the VIP screen must be next to these slots in order to capture any second or third measures attempted on SPs 60 or above.

3.15 How the Mini-Lab Screen Displays the Cursor

The cursor on the Mini-Lab begins at the Right Brachial site. When this reading is completed, use the arrow keys to position the cursor at the Right Posterior Tibial site. The cursor will move to the next sites automatically.

Rt. Brachial	1	Use arrow keys to position cursor at Left Posterior Tibial site.
Lt. Brachial	6	
Rt. Posterior Tibial	5	
Lt. Posterior Tibial	4	
Rt. Posterior Tibial	3	
Lt. Posterior Tibial	2	

3.16 Measurement of Systolic Pressures

60 Years and Above. SPs 60 years of age and above will have the measurements captured once at each of the three sites.

Right Brachial Systolic Blood Pressure

- Connect the air hose to the brachial cuff.
- Locate the right brachial artery using palpation. If you are unable to locate the pulse by palpation within 10 - 20 seconds, continue with the protocol and find the pulse

with the Doppler. On some occasions you may not be able to palpate the pulse but it will be easily located by Doppler.

- Apply a small amount of Doppler gel to the site.
- Locate the right brachial artery using the Doppler.
- Adjust size and position of tracing on screen with buttons on the face of the vascular testing module.
- Turn up the volume on the remote control.
- Manipulate the Doppler to get the best possible auditory signal and visual waveform.
- Press and hold inflate on the remote control.
- Inflate the cuff quickly to approximately 70-90 mmHg and then in 20-30 mmHg increments.
- Observe waveform for obliteration of pulse and listen for loss of auditory signal.
- When both the waveform and the auditory signal disappear, stop inflating.
- Press Bleed on the remote control once to deflate. Do not hold or press a second time.
- Watch the screen for the reappearance of the waveform and listen for the return of the auditory signal.
- When the waveform returns and you hear the auditory signal, allow at least 3 complexes to appear on the screen. Then press F9.
- Remove the Doppler and turn down the volume.
- Using the right arrow key, scroll back to select the spot where the waveform first reappeared and/or the auditory signal. *Select the beginning of the first waveform when the auditory signal first reappeared.*
- Press F10 to save.

NOTE: If the brachial systolic pressure is greater than 210 mmHg, the technician will send an observation referral to the physician. See Chapter 5, Section 5.1 for details.

Left Posterior Tibial Systolic Blood Pressure

- Connect the air hose to the cuff.
- Locate the left posterior tibial artery using palpation.
- Repeat the steps outlined above to obtain the left ankle blood pressure.

Right Posterior Tibial Systolic Blood Pressure

- Connect the air hose to the cuff.
- Locate the right posterior tibial artery using palpation.
- Repeat the steps outlined above to obtain the right ankle pressure.

NOTE: If either the left or right ankle pressures are greater than 255 mmHg, or if there is no pulse detected at one or both sites, no blood pressures can be obtained on the affected sites. If no blood pressure is obtained, the technician will need to record the reason for the missing blood pressure in ISIS. See Chapter 4 for data entry screen details.

40 - 59 Years Old. SPs 40 - 59 years of age will have the pressures captured twice at each of the three sites. Repeat the above measurements in the following sequence. Note that right brachial systolic pressure is at the end rather than the beginning of this sequence:

- Left Posterior Tibial Systolic Pressure;
- Right Posterior Tibial Systolic Pressure; and
- Right Brachial Systolic Pressure (move cursor on screen to position for second reading for right brachial systolic reading).

3.17 Completion of Test

As soon as the last blood pressure is measured, remove the blood pressure cuffs, wipe off excess gel from the arms and ankles and assist the SP to a sitting position. Let the SP sit on the side of the stretcher for a few moments to make sure s/he does not feel dizzy. While the SP is resting on the side of the stretcher, go through the VIP sequence to save the ABPI data. Click the 'Finish' button once the SP is ready to stand and walk.

After the SP has been taken to the coordinator's area or to the next exam, the LED room must be prepared for the next SP. The exam table paper must be changed, the cuffs should be cleaned, and the equipment and supplies must be organized.

The technician must wash his/her hands thoroughly before beginning the next exam.

3.18 Examples of Lower Extremity Abnormalities

The following photos are examples of some abnormalities that may be encountered during the lower extremity exam. Technicians are not expected to diagnose these problems but if abnormalities are noted, an observation referral may be sent to the physician who can then make the decision if further action is warranted. See Section 5.1 for a description of how to send an observation referral. Not all of the following examples are cause for exclusion. It is important to get as much information as possible on individuals with foot abnormalities as well as those without foot abnormalities. Individuals are excluded from all or part of the exam if performing the exam would cause severe discomfort or increase the severity of the abnormality, or if valid results could not be obtained because of the nature of the abnormality.



Figure 3-10. Pitting edema

Some medical conditions cause congestion and loss of fluid into the tissues resulting in a type of edema called pitting edema. Pressure on the skin with your fingers will leave a depression in the skin (pitting). This may be a reason for not measuring the systolic pressure in that ankle if the edema is severe enough or causes the SP discomfort when the cuff is applied.



Figure 3-11. Venous stasis

Venous stasis is not an exclusion for monofilament testing or ankle-brachial pressure measurement unless it causes discomfort for the SP.

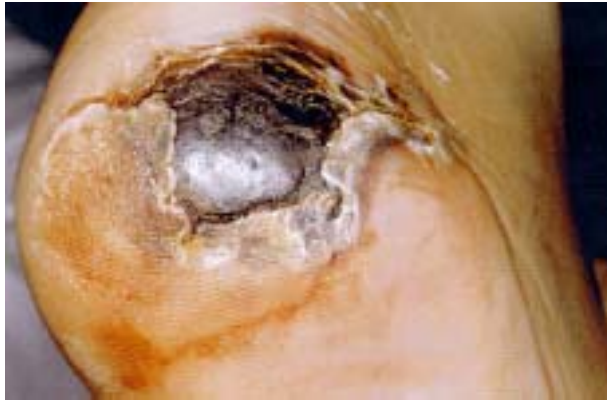


Figure 3-12. Black eschar

Any open or draining wounds and blackened areas should be referred to the physician. The physician will discuss this with the SP and make a decision about what action is needed.



Figure 3-13. Callus

The monofilament test would not be performed on a site that is covered by a callus.



Figure 3-14. Fungal infected great toe

This photo shows an infected great toe with a fungal nail. This infection would warrant an observation referral to the MEC physician.

4. DATA ENTRY SCREENS

4.1 Shared Exclusion Questions

Exhibit 4-1. Shared exclusion questions

The screenshot shows a software window titled "LED Stand 506 Session 506211 12/05/2008 01:30 pm - 05:30 pm". The window contains a form for "Preparation for ABPI". At the top, it displays patient information: "SP ID: _____ Name: _____ Age: 40 years Gender: Female Date: _____ Time: _____". The main section is "Shared Exclusion Questions" and includes the following fields and options:

- Do you have any amputations of your legs and feet other than toes? Yes No
- Where is the amputation?
- How much do you weigh without clothes or shoes? pounds
- Exam Preparation section with sub-sections:
 - Arm: Right Left Could Not Obtain Comments
 - Arm Cuff Size: Child Adult Large Adult Thigh Could Not Obtain Comments
 - Large adult selected due to poor thigh cuff fit? Yes No
 - Ankles: Right Left Both Could Not Obtain Comments
 - Ankle Cuff Size: Child Adult Large Adult Could Not Obtain Comments

At the bottom of the window, there are navigation buttons: "End of Section", "Done Exam", and "Quit". The status bar at the very bottom reads: "MEC Layer 12/6/08 Application: Ver 6.12.11A Not connected to Coordinator 10:22 AM".

- The Shared Exclusion Questions will be answered in the Household Interview and will be disabled once the data are entered.
- If the Shared Exclusion Questions have not been answered in the Household Interview, they will be enabled and will be answered in the MEC. These questions will be answered one time only in the MEC in the first exam where Shared Exclusions are asked.
- Some exams do not require all the shared exclusions. In this situation, there may be some questions answered in one exam and then disabled in the remaining exams.
- It is possible to have some Shared Exclusion Questions answered and disabled and others not answered and enabled. (Example: If the Shared Exclusion Questions are not answered in the Household Interview and the SP goes to Muscle Strength before Body Composition, the questions on amputation would be answered and disabled from Muscle Strength but the question on weight will remain unanswered and enabled.)
- If the Shared Exclusion Questions are answered in the Household Exam, the questions will appear answered and disabled. These responses cannot be changed in the MEC.
- If the responses excluded the SP from this exam, the SP would be blocked from LED by the Coordinator System and the SP would not be sent to this exam.
- The Component Status for LED for this SP would be set to Not Done with a comment specific to the reason for exclusion (safety exclusion, physical limitation, etc.).

- The safety/exclusion questions on the first screen are standard questions, not observations. If these two questions have not been asked in a previous component (completed and grayed out on the screen), you must read the question to the SP word-for-word and record the response. Although the responses may be obvious, they are not observations and in the interest of standardization across components, you must treat them as questions, not observations.
- If the answer to ‘Do you have any amputations of your fingers and toes?’ is no, the next question is disabled and the SP remains eligible for the exam.
- If the answer to the question ‘What is your current weight?’ is less than 400 pounds, the question is disabled and the SP remains eligible for the exam.
- If the exclusion questions are not answered in LED and the SP reports an amputation, the location of the amputation must be noted.

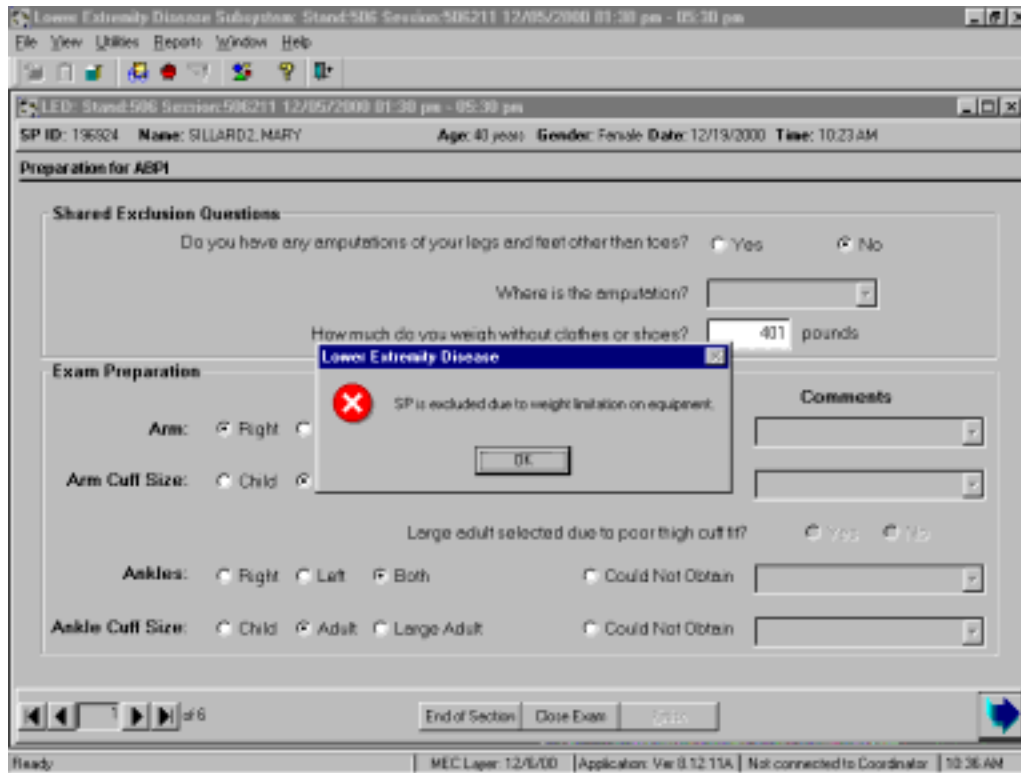
Exhibit 4-2. Shared exclusion questions – amputation

The screenshot displays the 'LED: Stand 506 Session:506211 12/05/2008 01:30 pm - 05:30 pm' window. The patient information at the top reads: 'SP ID: 130204 Name: GELLARD, HARRY Age: 40 years Gender: Female Date: 12/13/2000 Time: 10:23 AM'. The 'Preparation for ASP' section contains the following questions and options:

- Shared Exclusion Questions:**
 - Do you have any amputations of your legs and feet other than toes? Yes No
 - Where is the amputation? (Dropdown menu options: Right, Left, Both)
 - How much do you weigh without clothes or shoes?
- Exam Preparation:**
 - Arm: Right Left Could Not Obtain
 - Arm Duff Size: Child Adult Large Adult Thigh Could Not Obtain
 - Large adult selected due to poor high cuff? Yes No
 - Ankles: Right Left Both Could Not Obtain
 - Ankle Duff Size: Child Adult Large Adult Could Not Obtain

At the bottom, there are navigation buttons: 'End of Section', 'Close Exam', and 'Exit'. The status bar at the very bottom shows: 'Ready | MEC Layer 12/6/00 | Application Ver 8.12.114 | Not connected to Coordinator | 10:26 AM'.

Exhibit 4-3. Shared exclusion questions – weight limit



- If the answer to the question ‘What is your current weight?’ is more than 400 pounds, the SP is excluded from the exam.

4.2 Exam Preparation

Exam Preparation – Defaults

Exhibit 4-4. Shared exclusion questions – weight limit

The screenshot displays a software window titled "Lower Extremity Disease Subsystem: Stand 506 Session 506211 12/05/2000 01:30 pm - 05:30 pm". The window contains a menu bar (File, View, Queries, Reports, Window, Help) and a toolbar. Below the menu bar, a header section identifies the patient: "LED: Stand 506 Session 506211 12/05/2000 01:30 pm - 05:30 pm", "SP ID: 136324", "Name: SILLARD, MARY", "Age: 40 years", "Gender: Female", "Date: 12/13/2000", and "Time: 10:23 AM".

The main content area is titled "Preparation for ABPI" and is divided into two sections:

- Shared Exclusion Questions:** This section contains three questions:
 - "Do you have any amputations of your legs and feet other than toes?" with radio buttons for "Yes" and "No" (selected).
 - "Where is the amputation?" with a dropdown menu.
 - "How much do you weigh without clothes or shoes?" with a text input field followed by "pounds".
- Exam Preparation:** This section contains four rows of options, each with a "Comments" dropdown menu:
 - Arm:** Radio buttons for "Right" (selected) and "Left", and a "Could Not Obtain" option.
 - Arm Cuff Size:** Radio buttons for "Child", "Adult", "Large Adult", and "Thigh", and a "Could Not Obtain" option.
 - Ankles:** Radio buttons for "Right", "Left", and "Both" (selected), and a "Could Not Obtain" option.
 - Ankle Cuff Size:** Radio buttons for "Child", "Adult", and "Large Adult", and a "Could Not Obtain" option.

At the bottom of the window, there is a navigation bar with "End of Section", "Close Exam", and "Quit" buttons, and a status bar showing "Ready", "MEC Layer: 12/6/00", "Application: Ver 0.12.11A", "Not connected to Coordinator", and "10:25 AM".

In the Exam Preparation block:

- The right arm will be used for brachial pressure measurements unless there is a reason this arm should not be used. If the right arm cannot be used, use the left arm. The system is defaulted to 'Right.'
- There is no default for the Arm Cuff Size. Each SP must have the arm measured to select the correct cuff size.
- 'Ankles' is defaulted to 'Both.' Both ankles will be used for pressure measurement unless there is a reason one or both ankles should not be used.

- There is no default for the Ankle Cuff Size. The ankle cuff size is recorded automatically by ISIS based on the arm cuff size. If a child cuff is used on the arm, a child cuff will be used on both ankles. The same situation applies to the adult cuff. If a large adult or thigh cuff is used on the arm, a large adult cuff will be used on both ankles.

Exam Preparation – Arm

Exhibit 4-5. Exam preparation – comments for arm

- If the 'Arm' selected is 'Left,' a comment is required.
- The choices for comments are: lesion/bandage, rash, amputation, and other.
- See Section 3.3 for a description of reasons for not using the right arm or either arm.

Exhibit 4-6. Exam preparation – required entry for comments

- If 'Could Not Obtain' is selected for Arm and a comment is selected, the remaining questions on the screen are disabled. The SP is excluded from the ABPI part of the exam because the arm pressure will not be obtained.
- When the Arrow or Next Button is pressed, the system will display a message: 'The SP is excluded from ABPI due to physical limitation.'

Exam Preparation – Brachial Cuff Size

Exhibit 4-7. Exam preparation – arm cuff size

Lower Extremity Disease Subsystem: Stand 506 Session 506211 12/05/2000 01:30 pm - 05:30 pm

File View Queries Reports Window Help

LED: Stand 506 Session 506211 12/05/2000 01:30 pm - 05:30 pm

SP ID: 136324 Name: SILLARD, MARY Age: 40 years Gender: Female Date: 12/13/2000 Time: 10:39 AM

Preparation for ABPI

Shared Exclusion Questions

Do you have any amputations of your legs and feet other than toes? Yes No

Where is the amputation?

How much do you weigh without clothes or shoes? pounds

Exam Preparation

Arm: Right Left Could Not Obtain

Arm Cuff Size: Child Adult Large Adult Thigh Could Not Obtain

Large adult selected due to poor thigh cuff fit? Yes No

Ankles: Right Left Both Could Not Obtain

Ankle Cuff Size: Child Adult Large Adult Could Not Obtain

End of Section Close Exam Exit

Ready MEC Layer: 12/6/00 Application: Ver 0.12.11A Not connected to Coordinator 10:42 AM

- Select the arm cuff size based on the BP cuff size chart. Note that the size used on the arm will determine the size used on the ankle. The system will automatically select the ankle cuff size.
- If the measured size for the cuff is ‘Large Arm’ and due to the shape of the arm, it is impossible to position the cuff so that a measurement can be taken, select ‘CNO’ and ‘other’ as the comment on the drop-down menu. On the Component Status screen, select “Poor Cuff Fit” as the reason. It is not always possible to obtain a perfect cuff fit and but should always do the best you can. ‘Poor cuff fit’ should not have to be used frequently.
- All other reasons for not doing the brachial measurement should be coded under ‘CNO’ for ‘Arm’

Exhibit 4-8. Exam preparation – large adult for arm cuff size

LED: Stand 506 Session: 506211 12/05/2000 01:30 pm - 05:30 pm

SP ID: Name: Age: 40 years Gender: Female Date: 12/13/2000 Time:

Preparation for ABPI

Shared Exclusion Questions

Do you have any amputations of your legs and feet other than toes? Yes No

Where is the amputation?

How much do you weigh without clothes or shoes? 145 pounds

Exam Preparation

Arm: Right Left Could Not Obtain

Arm Cuff Size: Child Adult Large Adult Thigh Could Not Obtain

Large adult selected due to poor thigh cuff fit? Yes No

Ankles: Right Left Both Could Not Obtain

Ankle Cuff Size: Child Adult Large Adult Could Not Obtain

End of Section Close Exam Exit

Ready | MEC Layer: 12/6/00 | Application: Ver 0.12.11A | Not connected to Coordinator | 10:43 AM

- If 'Large Adult' is selected for Arm Cuff Size, the question 'Large adult selected due to poor thigh cuff fit?' will be enabled.

Exhibit 4-9. Poor thigh cuff fit

The screenshot shows a software window titled "LED: Stand 506 Session: 506211 12/05/2000 01:30 pm - 05:30 pm". The patient information includes: SP ID: [blank], Name: [blank], Age: 40 years, Gender: Female, Date: 12/13/2000, Time: [blank]. The section is titled "Preparation for ABPI".

Shared Exclusion Questions

Do you have any amputations of your legs and feet other than toes? Yes No

Where is the amputation? [dropdown menu]

How much do you weigh without clothes or shoes? 145 pounds

Exam Preparation

		Comments
Arm:	<input type="radio"/> Right <input checked="" type="radio"/> Left	<input type="radio"/> Could Not Obtain [dropdown menu]
Arm Cuff Size:	<input type="radio"/> Child <input type="radio"/> Adult <input checked="" type="radio"/> Large Adult <input type="radio"/> Thigh <input type="radio"/> Could Not Obtain	[dropdown menu]
Large adult selected due to poor thigh cuff fit?		<input checked="" type="radio"/> Yes <input type="radio"/> No
Ankles:	<input type="radio"/> Right <input type="radio"/> Left <input checked="" type="radio"/> Both	<input type="radio"/> Could Not Obtain [dropdown menu]
Ankle Cuff Size:	<input type="radio"/> Child <input type="radio"/> Adult <input checked="" type="radio"/> Large Adult	<input type="radio"/> Could Not Obtain [dropdown menu]

Navigation: [back] [forward] 1 of 6 [End of Section] [Close Exam] [Exit]

Status bar: Ready | MEC Layer: 12/6/00 | Application: Ver 0.12.11A | Not connected to Coordinator | 10:44 AM

- If the SP's arm falls into the thigh cuff range but the thigh cuff is a poor fit for the arm, the technician should use the large adult cuff and record the reason for the change in ISIS.
- The thigh cuff is considered to be a poor fit when the edge of the cuff covers the antecubital space and interferes with placement of the Doppler probe. The problem occurs when a SP has a very large but short arm.

Exhibit 4-10. Arm cuff size – thigh

The screenshot shows a software window titled "LED: Stand 506 Session: 506211 12/05/2000 01:30 pm - 05:30 pm". The window contains a form for "Preparation for ABPI". At the top, it displays patient information: "SP ID:", "Name:", "Age: 40 years", "Gender: Female", "Date: 12/13/2000", and "Time:". Below this is a section for "Shared Exclusion Questions" with the question "Do you have any amputations of your legs and feet other than toes?" and radio buttons for "Yes" and "No". There is also a dropdown menu for "Where is the amputation?" and a text input field for "How much do you weigh without clothes or shoes?" with the value "145" and the unit "pounds". The "Exam Preparation" section includes radio buttons for "Arm:" (Right, Left), "Arm Cuff Size:" (Child, Adult, Large Adult, Thigh), and "Ankles:" (Right, Left, Both). Each of these has a "Could Not Obtain" option and a corresponding "Comments" dropdown menu. A note states "Large adult selected due to poor thigh cuff fit?" with "Yes" and "No" radio buttons. The "Ankle Cuff Size:" options are Child, Adult, and Large Adult, each with a "Could Not Obtain" option and a "Comments" dropdown. At the bottom, there are navigation buttons (back, forward, etc.), "End of Section", "Close Exam", and "Done" buttons. The status bar at the very bottom shows "Ready", "MEC Layer: 12%/00", "Application: Ver 0.12.11A", "Not connected to Coordinator", and "10:43 AM".

- If the thigh cuff is selected for the arm, the cuff fit question will not be enabled. The large adult cuff will be selected for the ankles.

Exam Preparation – Ankles

Exhibit 4-11. Exam preparation – change to right ankle

The screenshot shows a software window titled "Lower Extremity Disease Subsystem: Stand:506 Session:506211 12/05/2000 01:30 pm - 05:30 pm". The interface includes a menu bar (File, View, Utilities, Reports, Window, Help) and a toolbar. The main content area is titled "LED: Stand:506 Session:506211 12/05/2000 01:30 pm - 05:30 pm" and contains patient information: "SP ID:", "Name:", "Age: 40 years", "Gender: Female", "Date: 12/19/2000", and "Time:". Below this is a section for "Preparation for ABPI" with "Shared Exclusion Questions": "Do you have any amputations of your legs and feet other than toes?" (radio buttons for Yes and No, with No selected), "Where is the amputation?" (a dropdown menu), and "How much do you weigh without clothes or shoes?" (a text box containing "145" followed by "pounds"). The "Exam Preparation" section includes: "Arm:" (radio buttons for Right, Left, and Could Not Obtain, with Right selected), "Arm Cuff Size:" (radio buttons for Child, Adult, Large Adult, Thigh, and Could Not Obtain, with Large Adult selected), "Ankles:" (radio buttons for Right, Left, Both, and Could Not Obtain, with Right selected), and "Ankle Cuff Size:" (radio buttons for Child, Adult, Large Adult, and Could Not Obtain). A "Comments" dropdown menu is open, showing options: "edema, lesions, bandages", "rash", "amputation", and "other". The interface also features navigation buttons (back, forward, home, end) and a status bar at the bottom with the text: "Ready | MEC Layer: 12/6/00 | Application: Ver 8.12.11A | Not connected to Coordinator | 10:40 AM".

- If only the right or left ankle can be used for pressure measurement, a comment is required.
- Select a comment from the drop-down menu.

Exhibit 4-12. Exam preparation – could not obtain for ankles

Lower Extremity Disease Subsystem: Stand:506 Session:506211 12/05/2000 01:30 pm - 05:30 pm

File View Utilities Reports Window Help

LED: Stand:506 Session:506211 12/05/2000 01:30 pm - 05:30 pm

SP ID: Name: Age: 40 years Gender: Female Date: 12/19/2000 Time:

Preparation for ABPI

Shared Exclusion Questions

Do you have any amputations of your legs and feet other than toes? Yes No

Where is the amputation?

How much do you weigh without clothes or shoes? pounds

Exam Preparation

Arm: Right Left Could Not Obtain

Arm Cuff Size: Child Adult Large Adult Thigh Could Not Obtain

Large adult selected due to poor thigh cuff fit? Yes No

Ankles: Right Left Both Could Not Obtain

Ankle Cuff Size: Child Adult Large Adult Could Not Obtain

Comments: edema, lesions, bandages, rash, amputation, other

Ready | MEC Layer: 12/6/00 | Application: Ver 8.12.11A | Not connected to Coordinator | 10:41 AM

- If 'Could Not Obtain' is selected for Ankles and a comment is selected, the remaining questions on the screen are disabled. The SP is excluded from the ABPI part of the exam because the ankle pressures will not be obtained.
- If it is impossible to position the cuff so that a measurement can be taken, select 'CNO' and 'other' as the comment on the drop-down menu. On the Component Status screen, select "Poor Cuff Fit" as the reason.
- When the Arrow or Next Button is pressed, the system will display a message: 'The SP is excluded from ABPI due to physical limitation.'
- After the Peripheral Neuropathy exam is completed, the 'Component Status' will be set to Partial with the comment 'physical limitation.'

Exam Preparation – Ankle Cuff Size

Exhibit 4-13. Exam preparation – ankle cuff size

Lower Extremity Disease - Subsystem: Stand-506 Session:506211 12/05/2008 01:30 pm - 05:30 pm

File View Utilities Reports Window Help

LED: Stand-506 Session:506211 12/05/2008 01:30 pm - 05:30 pm

SP ID: None Age: 40 years Gender: Female Date: 12/19/2000 Time:

Preparation for ABPI

Shared Exclusion Questions

Do you have any amputations of your legs and feet other than toes? Yes No

Where is the amputation?

How much do you weigh without clothes or shoes? pounds

Exam Preparation

		Comments
Arm:	<input checked="" type="radio"/> Right <input type="radio"/> Left <input type="radio"/> Could Not Obtain	<input type="text"/>
Arm Cuff Size:	<input type="radio"/> Child <input type="radio"/> Adult <input type="radio"/> Large Adult <input checked="" type="radio"/> Thigh <input type="radio"/> Could Not Obtain	<input type="text"/>
Large adult selected due to poor thigh cuff fit? <input type="radio"/> Yes <input checked="" type="radio"/> No		
Ankles:	<input type="radio"/> Right <input type="radio"/> Left <input checked="" type="radio"/> Both <input type="radio"/> Could Not Obtain	<input type="text"/>
Ankle Cuff Size:	<input type="radio"/> Child <input type="radio"/> Adult <input checked="" type="radio"/> Large Adult <input type="radio"/> Could Not Obtain	<input type="text"/>

Ready | MECLayer: 12/5/08 | Application: Ver 9.12.11A | Not connected to Coordinator | 10:43 AM

- Ankle cuff size is determined by the arm cuff size. ISIS will select 'Large Adult' for the ankles if 'Thigh' or 'Large Adult' is selected for the arm.

4.3 Abnormality Observations

Abnormality Observations – Left Foot

Exhibit 4-14. Abnormality observations – defaults

The screenshot shows a software window titled "LED: Stand 506 Session: 506211 12/05/2000 01:30 pm - 05:30 pm". Below the title bar is a menu bar with "File", "View", "Utilities", "Reports", "Window", and "Help". A toolbar contains icons for file operations. The main content area is titled "Abnormality Observations - Left Foot" and contains the following fields:

Field	Default Value	Radio Button	Comments
Amputation:	(none)	Could Not Obtain	
Bunions:	No	Could Not Obtain	
Lesion:	No	Could Not Obtain	
Lesion Site:			

At the bottom of the form, there are navigation buttons: "End of Section", "Close Exam", and "OK". The status bar at the very bottom shows "Ready", "MEC Layer: 12/6/00", "Application: Vnr 0.12.114", "Not connected to Coordinator", and "10:45 AM".

- Amputation is defaulted to 'None.'
- 'Bunions' and 'Lesions' are defaulted to 'No.'

Exhibit 4-15. Abnormality observations – left foot amputation – drop-down menu

The screenshot shows a form titled "Abnormality Observations - Left Foot". It contains the following fields and options:

- Amputation:** A dropdown menu with the following options: (none), entire foot, partial foot, great toe, other toe(s), and great toe AND other toe(s). To its right is a radio button labeled "Could Not Obtain".
- Bunions:** A dropdown menu with the same options as the Amputation field. To its right is a radio button labeled "Could Not Obtain".
- Lesion:** Radio buttons for "Yes" and "No" (with "No" selected). To its right is a radio button labeled "Could Not Obtain".
- Lesion Site:** A dropdown menu.
- Comments:** Three text input boxes, one for each of the Amputation, Bunions, and Lesion fields.

- If there is no amputation of the 'Left Foot,' the default remains at 'None.'
- If an amputation is present, select the appropriate level of amputation from the drop-down menu.
- The choices in the drop-down menu are: none, entire foot, partial foot, great toe, other toe(s), and great toe and other toe(s).

4.3.1 Amputation

Exhibit 4-16. Amputation – left (entire foot)

The screenshot shows a software interface titled "Abnormality Observations - Left Foot". It contains several input fields and radio buttons. The "Amputation" field is a dropdown menu with "entire foot" selected. To its right are radio buttons for "Could Not Obtain" (unselected). Below this are "Bunions" and "Lesion" fields, each with radio buttons for "Yes", "No", and "Could Not Obtain". The "Could Not Obtain" options are selected for both. To the right of these are dropdown menus containing the word "amputation". At the bottom left is a "Lesion Site" dropdown menu. At the bottom of the window are navigation controls: a set of arrows and "2 of 7", and buttons for "End of Section", "Close Exam", and "Next".

- If 'entire foot' is selected for amputation, the system will set Bunions and Lesions to 'Could Not Obtain' as default with the comment 'amputation.'
- The Peripheral Neuropathy screen for the Left foot will not appear.
- The ABPI screen will have the pressures for the Left Foot disabled.
- Press the Next button or press Enter to advance to the next screen.

Exhibit 4-17. Amputation – left – could not obtain comments

Abnormality Observations - Left Foot

Amputation: Could Not Obtain

Bunions: Yes No Could Not Obtain

Lesion: Yes No Could Not Obtain

Lesion Site:

Comments:

- If 'Could Not Obtain' is selected for Amputation, a comment from the drop-down menu is required.
- The choices from the drop-down menu are bandages, elastic stockings, casts, and other.

Exhibit 4-18. Abnormality observations – left foot amputation – partial foot

Lower Extremity Disease Subsystem: Stand 006 Session: 900471 12/01/1990 05:30 pm - 09:30 pm

SP ID: 154012 Name: Sanchez, Miguel Age: 44 years Gender: Male Date: 11/27/1990 Time: 03:25 PM

Abnormality Observations - Left Foot

Amputation: Could Not Obtain

Bunions: Yes No Could Not Obtain

Lesion: Yes No Could Not Obtain

Lesion Site:

Comments:

Ready

- If partial foot is selected for amputation, the system will set Bunions and Lesions to No. It is possible to have a Yes response or a 'Could Not Obtain' response for Bunions and Lesions. If this is the situation, change the response as appropriate.

- If 'Could Not Obtain' is selected, you are required to enter a comment for that item. If you do not enter a comment the system will display a message 'You are required to select a comment.'
- Press the Next Button or press Enter to advance to the next screen.

Exhibit 4-19. Abnormality observations – left foot amputation – great toe

- If great toe is selected for amputation, the system will set Bunions to No.
- It is possible to have a Yes or 'Could Not Obtain' response for Bunions and Lesions. If this is the situation, change the response as appropriate.
- If 'Could Not Obtain' is selected, you are required to enter a comment for that item. If you do not enter a comment the system will display a message 'You are required to select a comment.'
- When the Peripheral Neuropathy screen for the Left Foot comes up, the Hallux (Great Toe) will be disabled with 'Could Not Obtain' selected and 'Amputation' selected as the comment. See Exhibit 6-3.
- Press the Next Button or press Enter to advance to the next screen.

Exhibit 4-20. Abnormality observations - left foot amputation – other toes

Amputations: Could Not Obtain

Bunions: Yes No Could Not Obtain

Lesion: Yes No Could Not Obtain

Lesion Site:

End of Section Close Exam

- If Other Toes(s) is selected for amputation, the system will set Bunions and Lesions to No.
- It is possible to have a Yes or 'Could Not Obtain' response for Bunions and Lesions. If this is the situation, change the response as appropriate.
- If 'Could Not Obtain' is selected, you are required to enter a comment for that item. If you do not enter a comment the system will display a message 'You are required to select a comment.'
- Press the Forward Arrow or press Enter to advance to the next screen.

Exhibit 4-21. Abnormality observations – left foot amputation – great toes and other toes

Lower Extremity Disease Subsystem: Stand 806 Session: 988471 12/01/1998 05:30 pm - 05:30 pm

SP ID: 134812 Name: Sanchez, Miguel Age: 44 years Gender: Male Date: 11/27/1998 Time: 03:25 PM

Abnormality Observations: Left Foot

	Comments
Amputation: <input type="text" value="great toe AND other toe(s)"/> <input type="radio"/> Could Not Obtain	<input type="text"/>
Bunions: <input type="radio"/> Yes <input checked="" type="radio"/> No <input type="radio"/> Could Not Obtain	<input type="text"/>
Lesion: <input type="radio"/> Yes <input checked="" type="radio"/> No <input type="radio"/> Could Not Obtain	<input type="text"/>
Lesion Site: <input type="text"/>	

End of Section Close Exam Enter

Ready

- If Great Toe(s) and Other Toes(s) is selected for amputation, the system will set Bunions and Lesions to No.
- It is possible to have a Yes or 'Could Not Obtain' response for Bunions and Lesions. If this is the situation, change the response as appropriate.
- If 'Could Not Obtain' is selected, you are required to enter a comment for that item. If you do not enter a comment the system will display a message 'You are required to select a comment.'
- Press the Forward Arrow or press Enter to advance to the next screen.

4.3.2 Bunions

Exhibit 4-22. Abnormality observations – left foot bunions – comments

The screenshot shows a web form titled "Abnormality Observations - Left Foot". It contains several input fields and checkboxes. The "Amputation" field is a dropdown menu with "(none)" selected. Next to it is a "Could Not Obtain" checkbox. The "Bunions" section has three radio buttons: "Yes", "No", and "Could Not Obtain". The "Lesion" section has three radio buttons: "Yes", "No", and "Could Not Obtain". The "Lesion Site" field is a text input. To the right, there is a "Comments" field with a dropdown arrow. A dropdown menu is open, showing the following options: "bandage", "elastic stockings", "casts", "amputation", and "other".

- If Yes or 'Could Not Obtain' is selected for Bunions, you are required to enter a comment. The choices in the drop-down menu are bandage, elastic stockings, cast, amputation, and other.

4.3.3 Lesions

Exhibit 4-23. Abnormality observations – left foot lesion – comment drop-down menu

The screenshot shows the same web form as Exhibit 4-22. In this view, the "Bunions" section has "No" selected. The "Lesion" section has "No" selected. The "Comments" dropdown menu is open, showing the following options: "elastic stockings", "casts", "amputation", and "other".

- If 'Could Not Obtain' is selected for any item a comment is required.
- The choices in the drop-down menu are elastic stockings, casts, amputation, and other.
- See Section 3-6 for the definition of lesions used in this survey.

Exhibit 4-24. Abnormality observations – left foot lesions – drop-down menu

Abnormality Observations - Left Foot

Amputation: (none) Could Not Obtain

Bunions: Yes No Could Not Obtain

Lesion: Yes No Could Not Obtain

Lesion Site:
 side or bottom of foot
 top of toe(s)
 other

- If Yes is selected for Lesions, select the site of the lesion from the drop-down menu.
- The choices in the drop-down menu are: Side or bottom of the foot, Top of the toes(s) and Other.

Exhibit 4-25. Abnormality observations – left foot lesion ‘could not obtain’

Abnormality Observations - Left Foot

Amputation: (none) Could Not Obtain

Bunions: Yes No Could Not Obtain

Lesion: Yes No Could Not Obtain

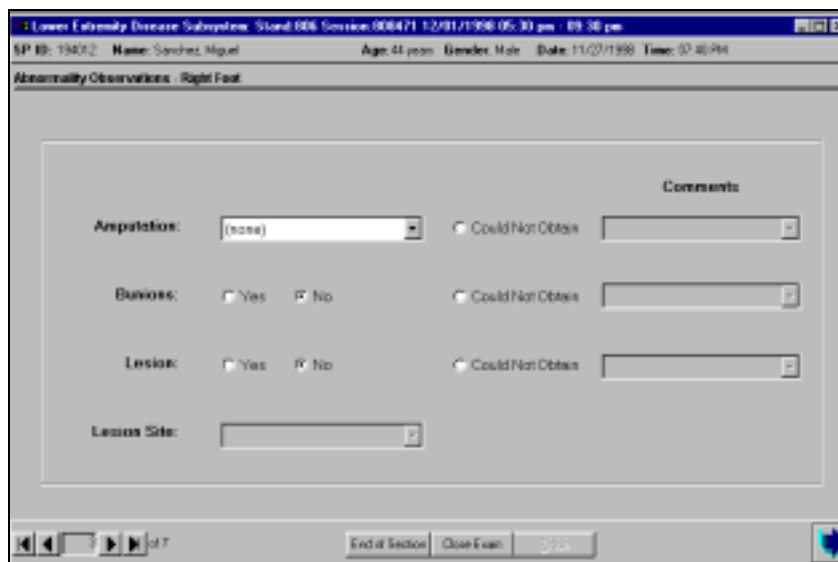
Lesion Site:

Lower Extremity Disease
 You must enter comments if 'could not obtain' is selected.
 OK

- If a comment is not selected and the Forward Arrow is clicked, the system will display a message: ‘You must enter comments if ‘Could Not Obtain’ is selected.’
- Click OK and select the appropriate comment from the drop-down menu.

Right Foot – Defaults

Exhibit 4-26. Abnormality observations – right foot amputation – none

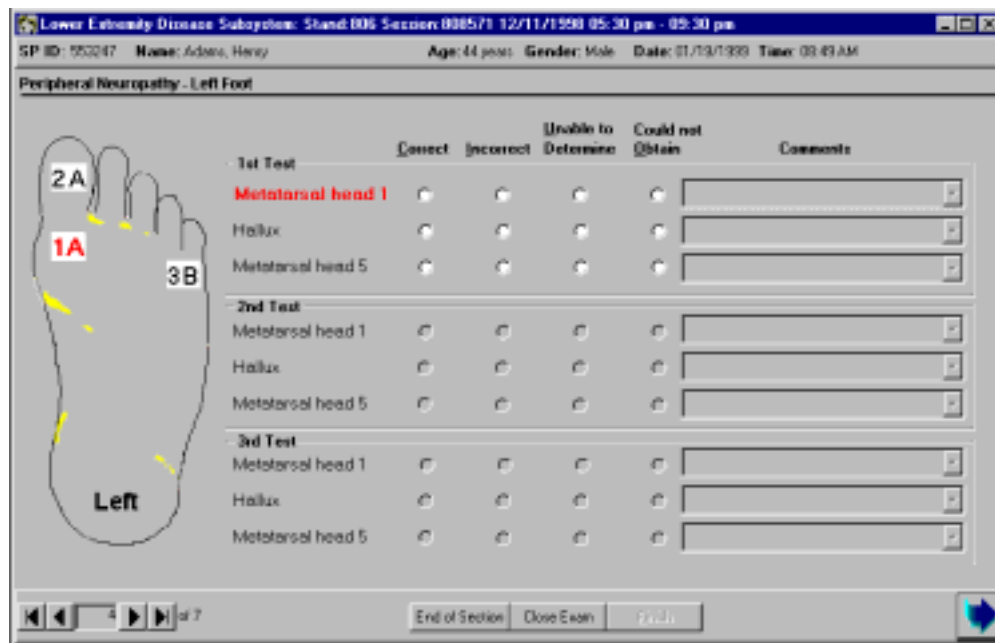


- The data entry screen functionality for the right foot is the same as the left foot.

4.4 Peripheral Neuropathy

Peripheral Neuropathy – Left Foot

Exhibit 4-27. Peripheral neuropathy – left foot



- This is the default screen for Peripheral Neuropathy.

- Three sites will be tested on each foot (Metatarsal Head 1, Metatarsal Head 5, and Hallux)
- The letters A and B are randomly assigned to the numbered sites.
- The sites are highlighted in the order in which they are to be tested.
- The possible responses are correct, incorrect, unable to determine, or ‘Could Not Obtain.’
- Number keys or letter keys may be used to enter these responses as follows:
 - Correct 1 or C
 - Incorrect 2 or I
 - Unable to Determine 3 or U
 - Could Not Obtain 4 or O

Exhibit 4-28. Peripheral neuropathy – left foot – correct response, site 1

	Correct	Incorrect	Unable to Determine	Could not Obtain	Comments
1st Test					
Metatarsal head 1	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Hallux	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Metatarsal head 5	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
2nd Test					
Metatarsal head 1	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Hallux	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Metatarsal head 5	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
3rd Test					
Metatarsal head 1	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Hallux	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Metatarsal head 5	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	

- When performing the monofilament test, look on the screen to see which site is highlighted.
- In this example, Test Site #1 is Metatarsal Head 1.

- The interval for Site 1 is A.
- Both are highlighted in red.
- Use the monofilament to test Metatarsal Head 1 on interval A.
- If the SP correctly identifies the interval in which the stimulus was applied, Type '1' as a short-cut key to indicate 'Correct.'
- Once the response is entered, the system highlights the next site to be tested.
- The site number and the interval in which to apply the stimulus is also highlighted.
- The second site to test is the Hallux and the interval in which to apply the stimulus is A.

Exhibit 4-29. Peripheral neuropathy – left foot – correct response, site 2

Lower Extremity Disease 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: 01/19/1999 Time: 08:49 AM

Peripheral Neuropathy - Left Foot

	Correct	Incorrect	Unable to Determine	Could not Obtain	Comments
1st Test					
Metatarsal head 1	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Hallux	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Metatarsal head 5	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
2nd Test					
Metatarsal head 1	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Hallux	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Metatarsal head 5	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
3rd Test					
Metatarsal head 1	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Hallux	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Metatarsal head 5	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	

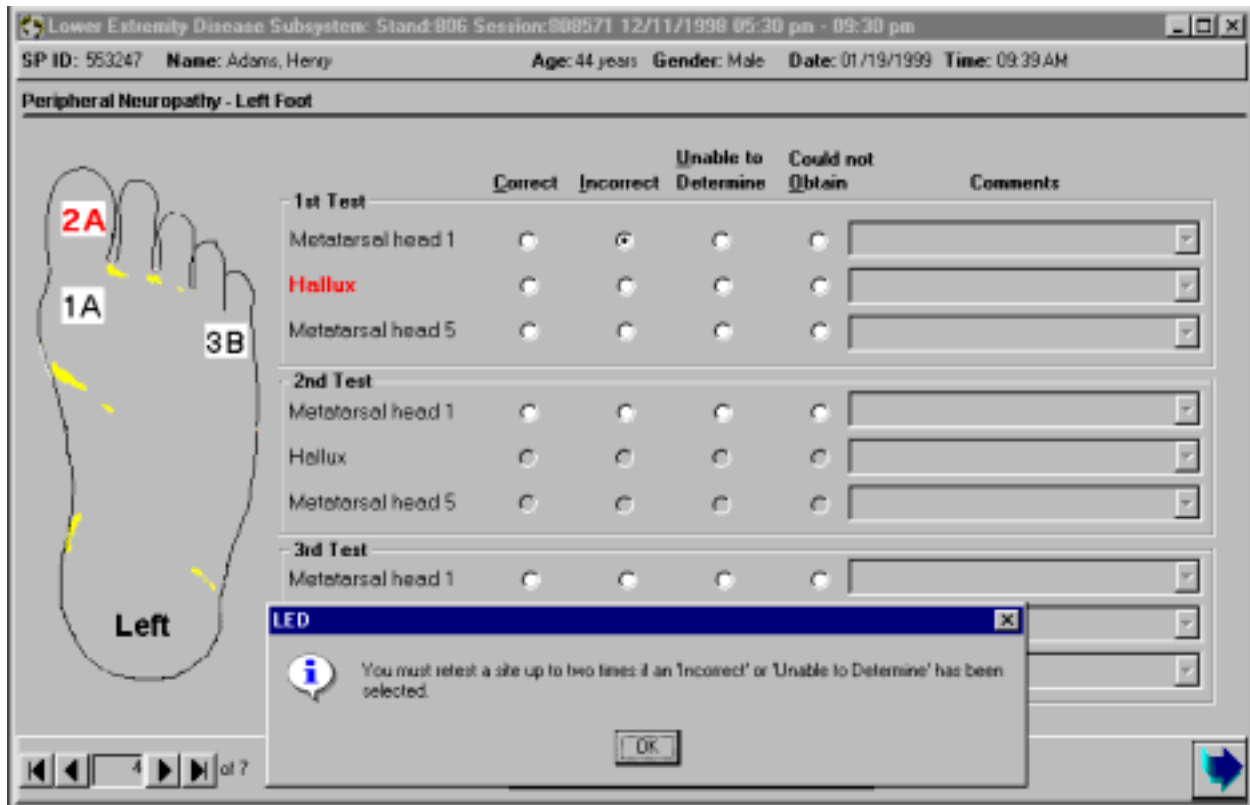
Left

4 of 7

End of Section Close Exam Exit

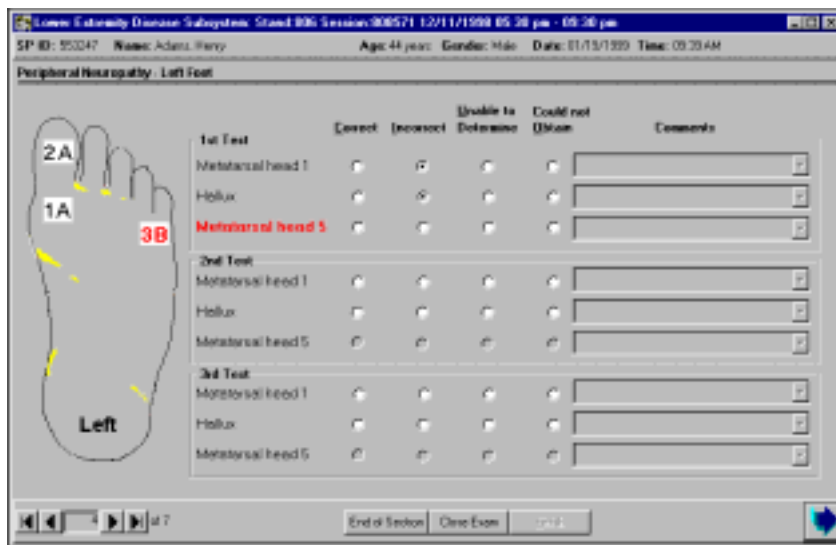
- Enter the response for Site 2 (Hallux).
- The system will highlight the third site to be tested.
- In this example, the site is Metatarsal Head 5 and the interval in which to apply the stimulus is B.

Exhibit 4-30. Peripheral neuropathy – incorrect response message



- If the response is incorrect, type '2' to indicate the response was incorrect.
- If the response is 'incorrect', the system will display a message: 'You must retest a site up to two times if 'Incorrect' or 'Unable to Determine' has been selected.'
- The system will enable the 2nd and 3rd test fields for that site.
- Test Sites #2 and #3 will be tested in sequence. All three sites will be tested once before the second set of tests is done on sites that need to be retested.
- The system will highlight the site to be tested next.
- When all 3 sites have been tested once, the system will go to the 2nd set of tests.
- The 2nd set of tests will be tested in sequence followed by the third set of tests if necessary.

Exhibit 4-31. Peripheral neuropathy – incorrect response on two sites



- If the second site is also an incorrect response, the system will enable the 2nd and 3rd test fields for that site. A message will be displayed again and the system will highlight the next site to be tested.

Exhibit 4-32. Peripheral neuropathy – incorrect responses on three sites



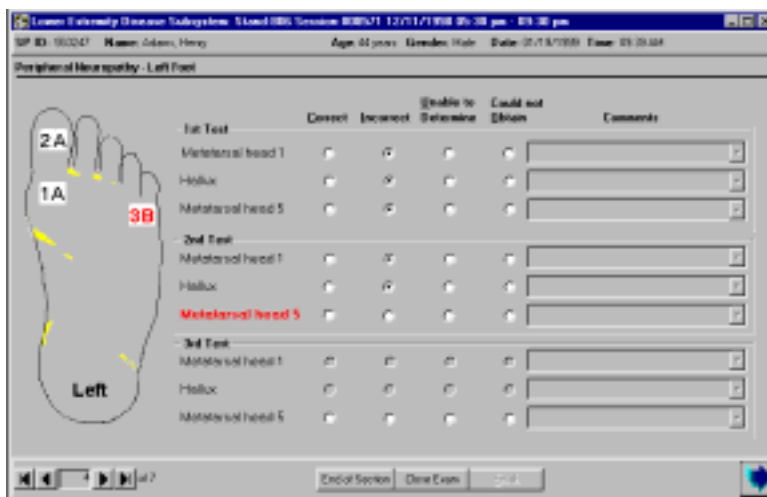
- If the third site is also an incorrect response, the system will enable the 2nd and 3rd test fields for that site. A message will be displayed again and the system will highlight the next site to be tested.

Exhibit 4-33. Peripheral neuropathy – incorrect responses same site



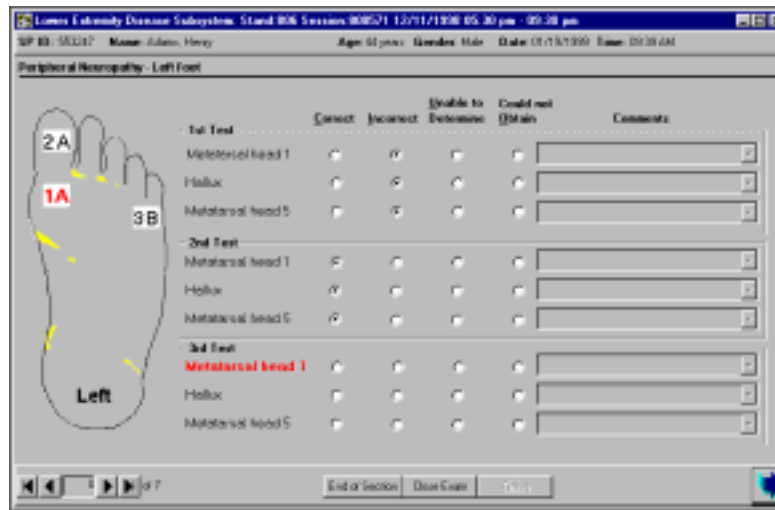
- If the response to site 1 is 'Incorrect' and the response to the 2nd test on that site is also 'Incorrect,' the field for the 3rd test on that site is disabled.
- Once there are two similar responses to a site, the 3rd test on that site is not necessary.

Exhibit 4-34. Peripheral neuropathy – 2nd test, incorrect responses



- If the response to site 2 is 'Incorrect' and the response to the 2nd test on that site is also 'Incorrect,' the field for the 3rd test on that site is disabled.
- As above, once there are two similar responses to a site, the 3rd test on that site is not necessary.

Exhibit 4-35. Peripheral neuropathy – 3rd test on a site



- If the response to the first test is 'Incorrect' and the response to the 2nd Test is 'Correct,' the system will enable the 3rd Test field for that site.
- You must have two similar responses on each site.

Exhibit 4-36. Peripheral neuropathy – normal sensation

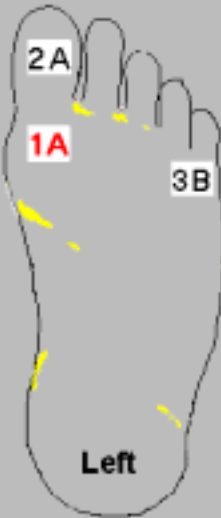


- In the above screen, 'Incorrect' responses were given for all 3 sites on the first test.
- All sites need to be tested a second time.
- If all sites are 'Correct' on the 2nd Test, all sites need to be tested a third time.
- If 'Correct' responses were given for all sites on the 2nd and 3rd Tests, each of the sites would be defined as sensate or having normal sensation.

Exhibit 4-37. Peripheral Neuropathy – decreased sensation

Lower Extremity Disease 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: 01/19/1999 Time: 09:39 AM

Peripheral Neuropathy - Left Foot



	Correct	Incorrect	Unable to Determine	Could not Obtain	Comments
1st Test					
Metatarsal head 1	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Hellux	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Metatarsal head 5	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	
2nd Test					
Metatarsal head 1	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Hellux	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Metatarsal head 5	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
3rd Test					
Metatarsal head 1	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Hellux	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Metatarsal head 5	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	

Left

4 of 7

End of Section Close Exam Exit

- In the above screen, 'Incorrect' responses were given for all 3 sites on the first test.
- All sites need to be tested a second time.
- If all sites are 'Correct' on the 2nd Test, all sites need to be tested a third time.
- If 'Incorrect' responses were given for all sites on the 1st and 3rd Tests, each of the sites would be defined as insensate or having decreased sensation.

Exhibit 4-38. Peripheral neuropathy – unable to determine

Lower Extremity Disease Subsystem: Stand:906 Session:808571 12/11/1998 05:30 pm - 09:30 pm
 SP ID: 553247 Name: Adams, Henry Age: 44 years Gender: Male Date: 01/19/1999 Time: 09:50 AM

Peripheral Neuropathy - Left Foot

	Correct	Incorrect	Unable to Determine	Could not Obtain	Comments
1st Test					
Metatarsal head 1	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	
Hallux	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Metatarsal head 5	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
2nd Test					
Metatarsal head 1	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Hallux	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Metatarsal head 5	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
3rd Test					
Metatarsal head 1	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Hallux	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Metatarsal head 5	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	

LED
 You must retest a site up to two times if an 'Incorrect' or 'Unable to Determine' has been selected.
 OK

- ‘Unable to Determine’ works the same way as ‘Incorrect.’
- If ‘Unable to Determine’ is selected, the system displays the message “You must retest a site up to two times if an ‘Incorrect’ or ‘Unable to Determine’ is selected.”
- If ‘Incorrect’ is selected for Test 1 and ‘Unable to Determine’ is selected for Test 2, the system will disable the field for Test 3 for that site. In this situation, it is not necessary to test this site a third time.

Exhibit 4-39. Peripheral neuropathy – data entry (1)

	Correct	Incorrect	Unable to Determine	Could not Obtain	Comments
1st Test					
Metatarsal head 1	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Hallux	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Metatarsal head 5	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	
2nd Test					
Metatarsal head 1	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	
Hallux	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Metatarsal head 5	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
3rd Test					
Metatarsal head 1	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Hallux	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Metatarsal head 5	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	

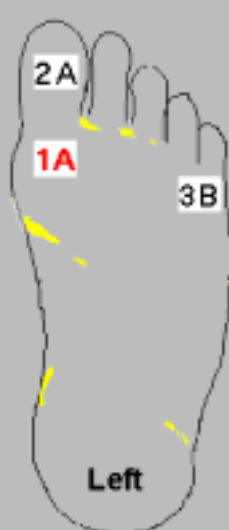
- In this example, Metatarsal Head 1 is highlighted first. The 1st Test for Metatarsal Head 1 was ‘Incorrect.’ This site has to be tested up to two more times until two similar responses are given for this site.
- Hallux is highlighted next and the 1st Test for Hallux is completed. An ‘Incorrect’ response is given for this site so this site will have to be tested up to two more times until two similar responses are given for this site.
- Metatarsal Head 5 is highlighted next and the 1st Test for Metatarsal Head 5 is completed. An ‘Incorrect’ response is given for this site so this site will have to be tested up to two more times until two similar responses are given for this site.
- The system highlights Metatarsal Head 1 for the 2nd Test. An ‘Unable to Determine’ response is given for this test. One ‘Incorrect’ response for Test 1 and 1 ‘Unable to Determine’ response for Test 2 are two similar responses so this site does not have to be tested again. This site would be defined as insensate.
- The system highlights Hallux for the 2nd Test on that site. A ‘Correct’ response is given. One ‘Incorrect’ response and one ‘Correct’ are dissimilar responses so this site will have to be tested a third time.

Exhibit 4-40. Peripheral neuropathy data entry (2)

Lower Extremity Disease Subsystem: Stand:006 Session:800571 12/11/1998 05:30 pm - 09:30 pm

SP ID: 659514 Name: Washington, Oliver Age: 40 years Gender: Male Date: 01/26/1999 Time: 07:35 PM

Peripheral Neuropathy - Left Foot



	Correct	Incorrect	Unable to Determine	Could not Obtain	Comments
1st Test					
Metatarsal head 1	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Hallux	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Metatarsal head 5	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	
2nd Test					
Metatarsal head 1	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	
Hallux	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Metatarsal head 5	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
3rd Test					
Metatarsal head 1	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Hallux	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	
Metatarsal head 5	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	

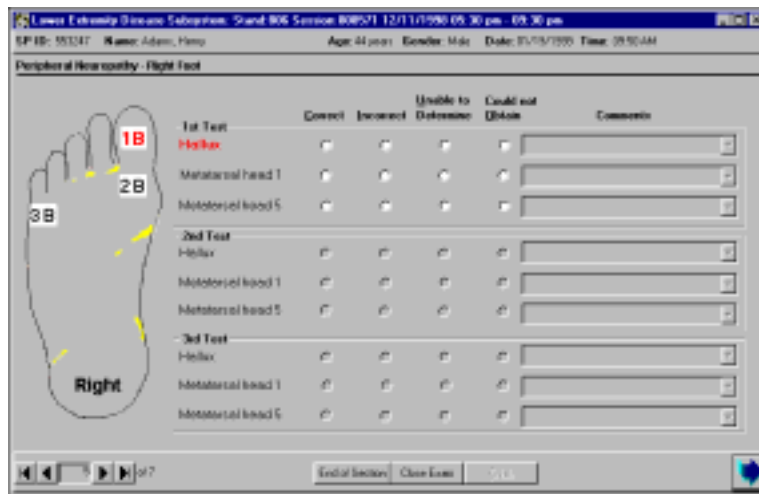
4 of 7

End of Section Close Exam Exit

- The system highlights Metatarsal Head 5 for the 2nd test on that site. The response is 'Correct.' One 'Incorrect' response and one 'Correct' are dissimilar responses so this site will have to be tested a third time.
- Metatarsal Head 1 does not require Test 3. That site is disabled for Test 3.
- The system highlights the Hallux for the 3rd Test on that site. The response is 'Unable to Determine.' One 'Incorrect' from Test 1 and one 'Unable to Determine' from Test 3 are two similar responses so this site will be defined as insensate.
- The system highlights Metatarsal Head 5 for the 3rd Test on that site. The response is 'Correct.' This site will be defined as sensate because it had two 'Correct' responses.
- Note that a 'Correct' response on the 1st Test is sufficient to define that site as sensate. In this situation, that site would not have to be tested again. If the response to the 1st Test is 'Incorrect' or 'Unable to Determine,' and the response to the 2nd test is 'Correct,' the site would have to be tested a third time to get 2 similar responses.

Peripheral Neuropathy – Right Foot

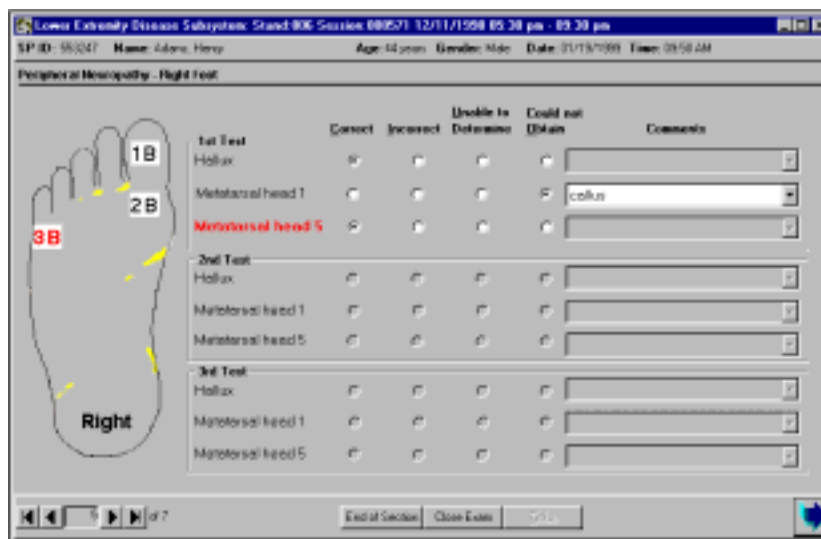
Exhibit 4-41. Peripheral neuropathy – right foot



- The data entry functionality for Peripheral Neuropathy - Right Foot is the same as for the Peripheral Neuropathy - Left Foot.

4.4.1 Peripheral Neuropathy - Could Not Obtain

Exhibit 4-42. Peripheral neuropathy – could not obtain



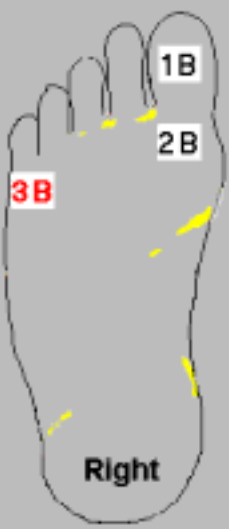
- If 'Could Not Obtain' is selected, a comment is required.
- If a comment is not selected and the Next Button is pressed, the system will display a message "You must enter comments if 'Could Not Obtain' is selected."
- Click OK and select a comment from the Comments drop-down menu.

Exhibit 4-43. Peripheral neuropathy – callus

Lower Extremity Disease Subsystem: Stand: 806 Session: 908571 12/11/1998 05:30 pm - 09:30 pm

SIP ID: 553247 Name: Adams, Henry Age: 44 years Gender: Male Date: 01/19/1999 Time: 09:50 AM

Peripheral Neuropathy - Right Foot



	Correct	Incorrect	Unable to Determine	Could not Obtain	Comments
1st Test					
Hellux	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Metatarsal head 1	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	callus
Metatarsal head 5	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
2nd Test					
Hellux	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Metatarsal head 1	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Metatarsal head 5	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
3rd Test					
Hellux	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Metatarsal head 1	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Metatarsal head 5	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	

5 of 7

End of Section Close Exam Exit

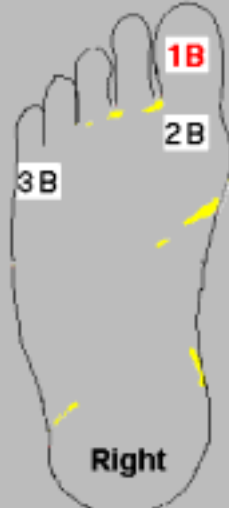
- If the site to be tested is covered by a callus, do not test that site.
- Select 'Could Not Obtain' and pull down the 'Comments' drop-down menu.
- Select 'Callus' from the drop-down menu list.

Exhibit 4-44. Peripheral neuropathy – lesions, bandages, elastic stockings

Lower Extremity Disease 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: 01/19/1999 Time: 09:50 AM

Peripheral Neuropathy - Right Foot



	Correct	Incorrect	Unable to Determine	Could not Obtain	Comments
1st Test					
HALLUX	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Metatarsal head 1	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Metatarsal head 5	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	lesions, bandages, elastic stockings
2nd Test					
HALLUX	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Metatarsal head 1	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Metatarsal head 5	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
3rd Test					
HALLUX	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Metatarsal head 1	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Metatarsal head 5	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	

5 of 7

End of Section Close Exam Finish

- If the site to be tested is covered by a bandage, dressing, elastic stocking, do not remove the covering.
- Select 'Could Not Obtain' for that site (and any other site affected by the covering).
- Select 'Lesions, Bandages, Elastic Stockings' from the 'Comments' drop-down list.
- If the site to be tested has a lesion on that area, do not test that site.
- Select 'Could Not Obtain' for that site (and any other site affected by the lesion).
- Select 'Lesions, Bandages, Elastic Stockings' from the 'Comments' drop-down list.

Exhibit 4-45. Peripheral neuropathy – amputation

Test	Correct	Incorrect	Unable to Determine	Could not Obtain	Comments
1st Test Hallux	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	amputation
Metatarsal head 1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Metatarsal head 5	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
2nd Test Hallux	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Metatarsal head 1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Metatarsal head 5	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
3rd Test Hallux	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Metatarsal head 1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Metatarsal head 5	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

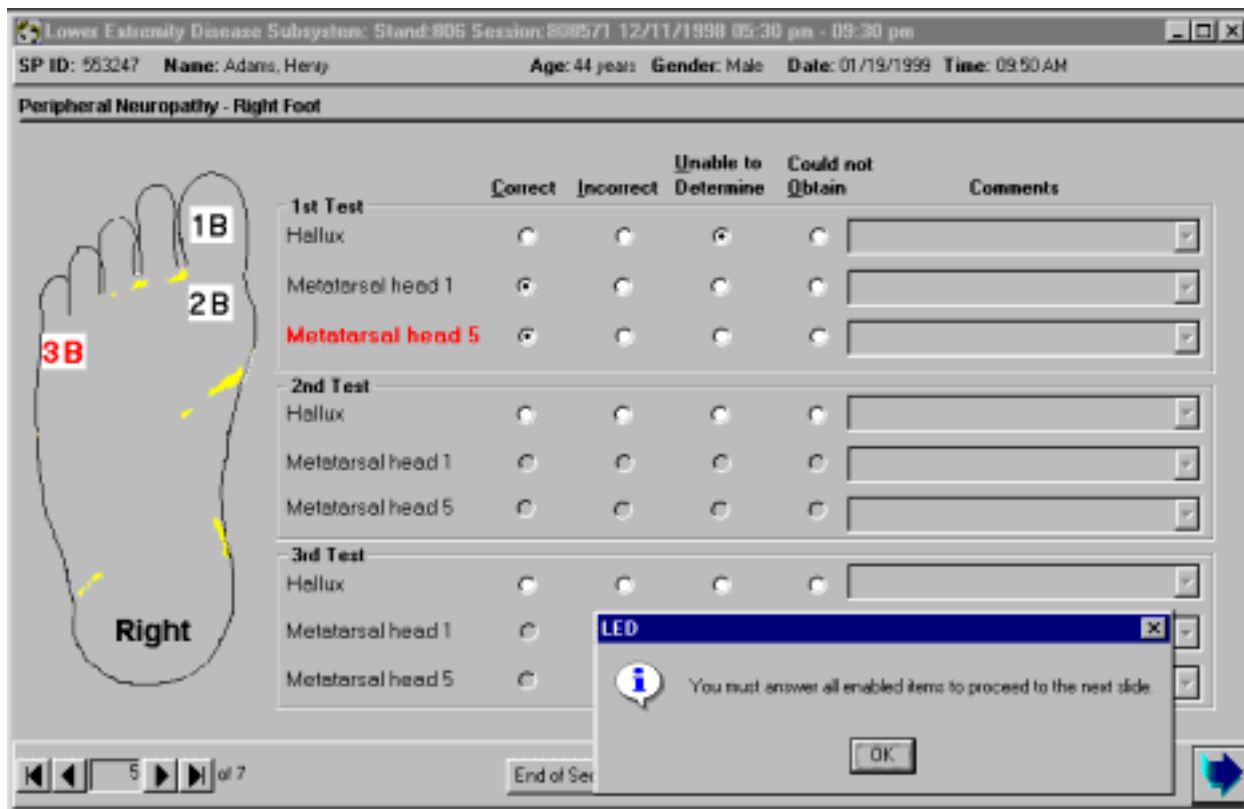
- If the Hallux (Great Toe) has been amputated, select 'Could Not Obtain' for that site.
- Select 'Amputation' from the 'Comments' drop-down menu.

Exhibit 4-46. Peripheral neuropathy could not obtain (3 sites)

Test	Correct	Incorrect	Unable to Determine	Could not Obtain	Comments
1st Test Hallux	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	lesions, bandages, elastic stockings
Metatarsal head 1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	lesions, bandages, elastic stockings
Metatarsal head 5	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	lesions, bandages, elastic stockings
2nd Test Hallux	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Metatarsal head 1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Metatarsal head 5	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
3rd Test Hallux	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Metatarsal head 1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Metatarsal head 5	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

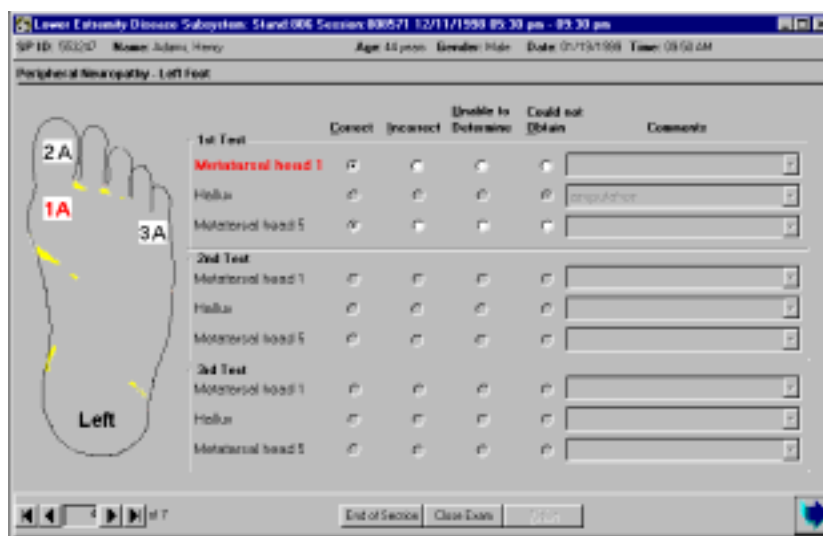
- If all three sites are affected, select 'Could Not Obtain' for all sites and select the appropriate comment from the 'Comments' drop-down menu.

Exhibit 4-47. Peripheral neuropathy – required response



- You are required to enter a response for all sites before proceeding to the next slide.
- If a response is not entered and the Next Button is pressed, the system will display a message ‘You must answer all enabled items before proceeding to the next slide.’

Exhibit 4-48. Peripheral neuropathy – hallux amputation, left foot



- If 'Great Toe' is selected for 'Amputation,' Left Foot, the system will set Hallux to 'Could Not Obtain' with the comment 'amputation.' This will be disabled and cannot be edited.

Exhibit 4-49. Peripheral neuropathy – hallux amputation – right foot

Test	1st Test			Comments
	Correct	Incorrect	Unable to Obtain	
Hallux	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	amputation
Metatarsal head 1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Metatarsal head 5	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
2nd Test				
Hallux	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Metatarsal head 1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Metatarsal head 5	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
3rd Test				
Hallux	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Metatarsal head 1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Metatarsal head 5	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

- If 'Great Toe' is selected for 'Amputation,' Right Foot, the system will set Hallux to 'Could Not Obtain' with the comment 'amputation.' This will be disabled and cannot be edited.

4.4.2 Peripheral Neuropathy - Technical Problems

Exhibit 4-50. Peripheral neuropathy – technical problems (1)



- There are several problems that may occur when performing the monofilament test. These problems have the potential of giving invalid results for the test. These problems are:
 - The monofilament may not have been applied with the standard amount of force.
 - The monofilament may slip off the site being tested.
 - The pressure may have been applied on the wrong interval.
 - The pressure may have been applied on both intervals.
- If any of the above situations occur or if any other technical problem occurs during monofilament testing, the technician should enter 'Could Not Obtain' with the comment 'technical problem.'
- In this situation the system will enable the 2nd and 3rd test for this site. This site will be tested again twice in sequence with the other sites.
- Note that this 'Could Not Obtain' response with the comment 'technical problem' is an exception to the usual way a 'Could Not Obtain' response is treated in this test. In all other situations, if 'Could Not Obtain' were selected for a site on the 1st Test, the 2nd and 3rd Tests for this site would be disabled.

Exhibit 4-51. Peripheral neuropathy – technical problems (2)

Lower Extremity Disease Subsystem: Stand:806 Session:808571 12/11/1998 05:30 pm - 09:30 pm

SP ID: 536053 Name: Washington, Matthew Age: 40 years Gender: Male Date: 01/20/1999 Time: 07:15 AM

Peripheral Neuropathy - Left Foot

	Correct	Incorrect	Unable to Determine	Could not Obtain	Comments
1st Test					
Metatarsal head 1	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	technical problem
Hallux	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Metatarsal head 5	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
2nd Test					
Metatarsal head 1	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Hallux	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Metatarsal head 5	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
3rd Test					
Metatarsal head 1	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Hallux	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Metatarsal head 5	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	

Left

4 of 7

End of Section Close Exam Refresh

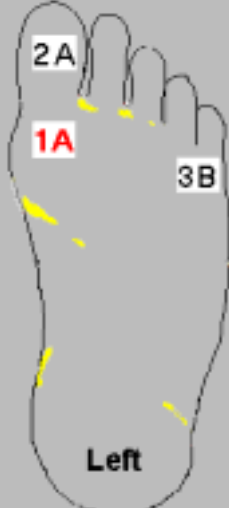
- In this example, the 1st Test for Metatarsal Head 1 is 'Could Not Obtain' with the comment 'technical problem.' When the 2nd Test is done, the result is 'Correct.'
- This test has to be repeated on that site another time to get 2 similar responses. If the 3rd test result is 'Correct,' that site will be defined as sensate.
- Note that if 'Correct' is obtained on the first test, the test does not have to be repeated. BUT, if 'another response is obtained on the first test and 'Correct' is obtained on the second test, the test must be repeated again on that site to get 2 similar responses on that site.

Exhibit 4-52. Peripheral neuropathy – technical problems (3)

Lower Extremity Disease Subsystem: Stand: 806 Session: 808571 12/11/1998 05:30 pm - 09:30 pm

SP ID: 536053 Name: Washington, Matthew Age: 40 years Gender: Male Date: 01/20/1999 Time: 07:15 AM

Peripheral Neuropathy - Left Foot



	Correct	Incorrect	Unable to Determine	Could not Obtain	Comments
1st Test					
Metatarsal head 1	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	technical problem
Hallux	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Metatarsal head 5	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
2nd Test					
Metatarsal head 1	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Hallux	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Metatarsal head 5	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
3rd Test					
Metatarsal head 1	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Hallux	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Metatarsal head 5	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	

Left

4 of 7

End of Section Close Exam Finish

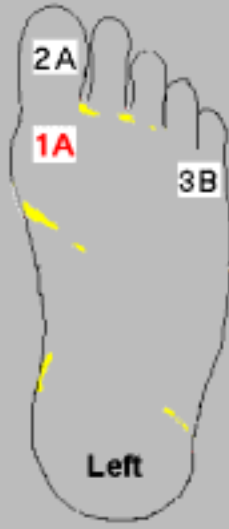
- In this example, the 1st Test for Metatarsal Head 1 is 'Could Not Obtain' with the comment 'technical problem.' When the 2nd Test is done, the result is 'Incorrect.'
- This test has to be repeated on that site another time to get 2 similar responses. If the 3rd test result is 'Incorrect,' that site will be defined as insensate.

Exhibit 4-53. Peripheral neuropathy – technical problems (4)

Lower Extremity Disease Subsystem: Stand:806 Session:8085/1 12/11/1998 05:30 pm - 09:30 pm

SP ID: 536053 Name: Washington, Matthew Age: 40 years Gender: Male Date: 01/20/1999 Time: 07:15 AM

Peripheral Neuropathy - Left Foot



	Correct	Incorrect	Unable to Determine	Could not Obtain	Comments
1st Test					
Metatarsal head 1	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	technical problem
Hallux	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Metatarsal head 5	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
2nd Test					
Metatarsal head 1	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	technical problem
Hallux	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Metatarsal head 5	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
3rd Test					
Metatarsal head 1	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Hallux	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Metatarsal head 5	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	

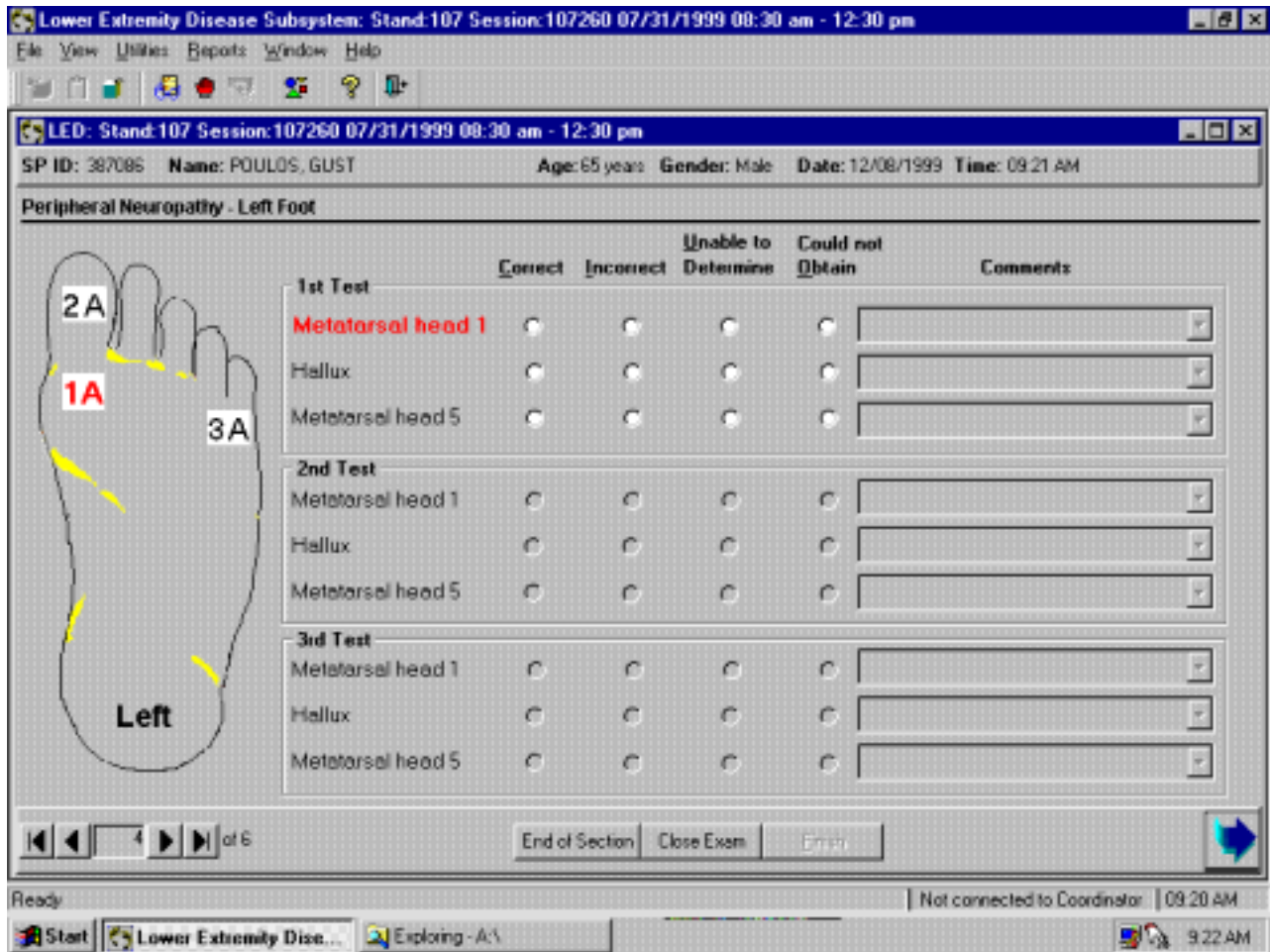
4 of 7

End of Section Close Exam Finish

- If a 'technical problem' is encountered twice for the same site, the 3rd Test will be enabled for that site. For referral and Report of Findings purposes, the site will not be defined as sensate or insensate.

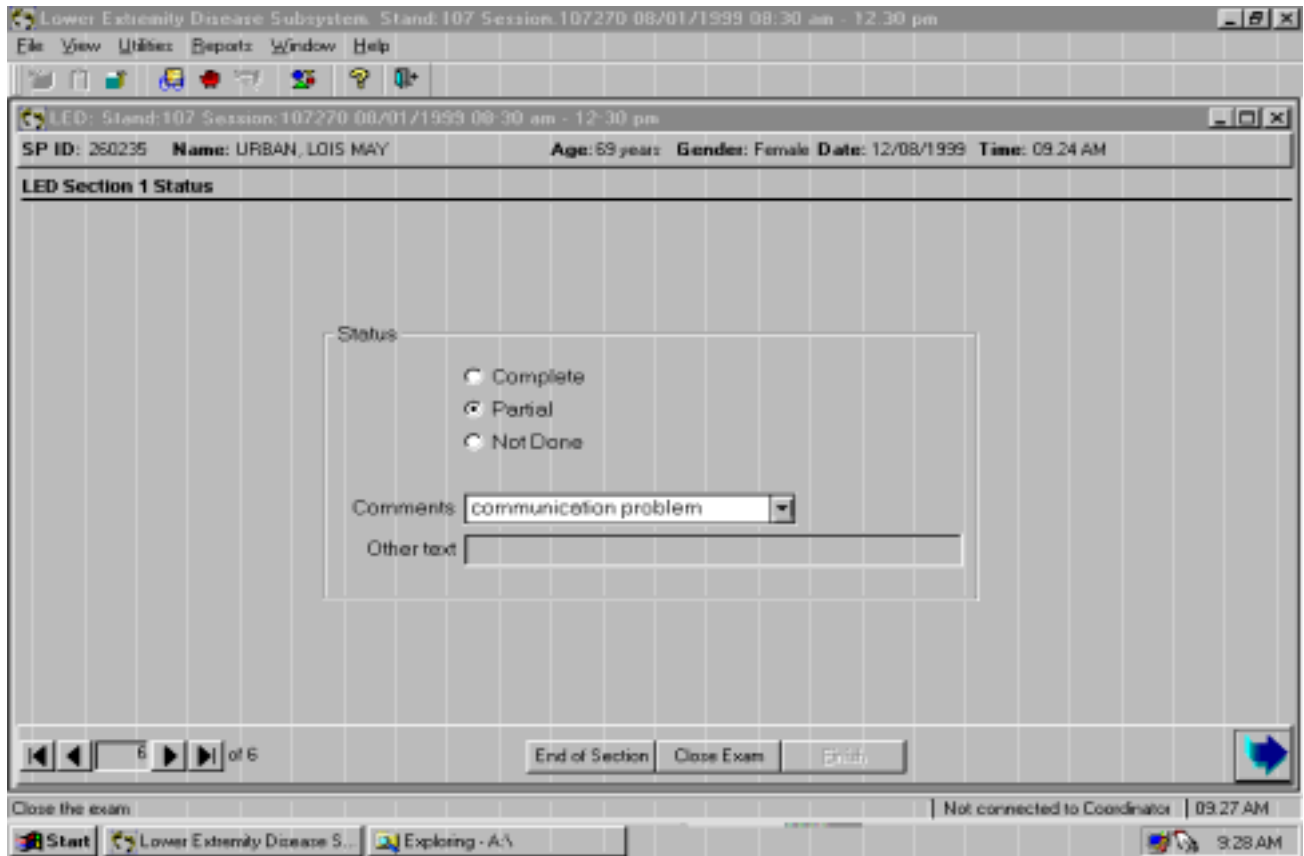
4.4.3 End of Section 1 – Partial Status

Exhibit 4-54. Peripheral neuropathy – end of section



- To skip the peripheral neuropathy section for SPs who cannot follow the standard explanation, click on the “End of Section” button at the bottom of the first peripheral neuropathy screen. This will end the first section of the LED exam and allow the technician to go directly into Section 2, the ankle-brachial pressure index.

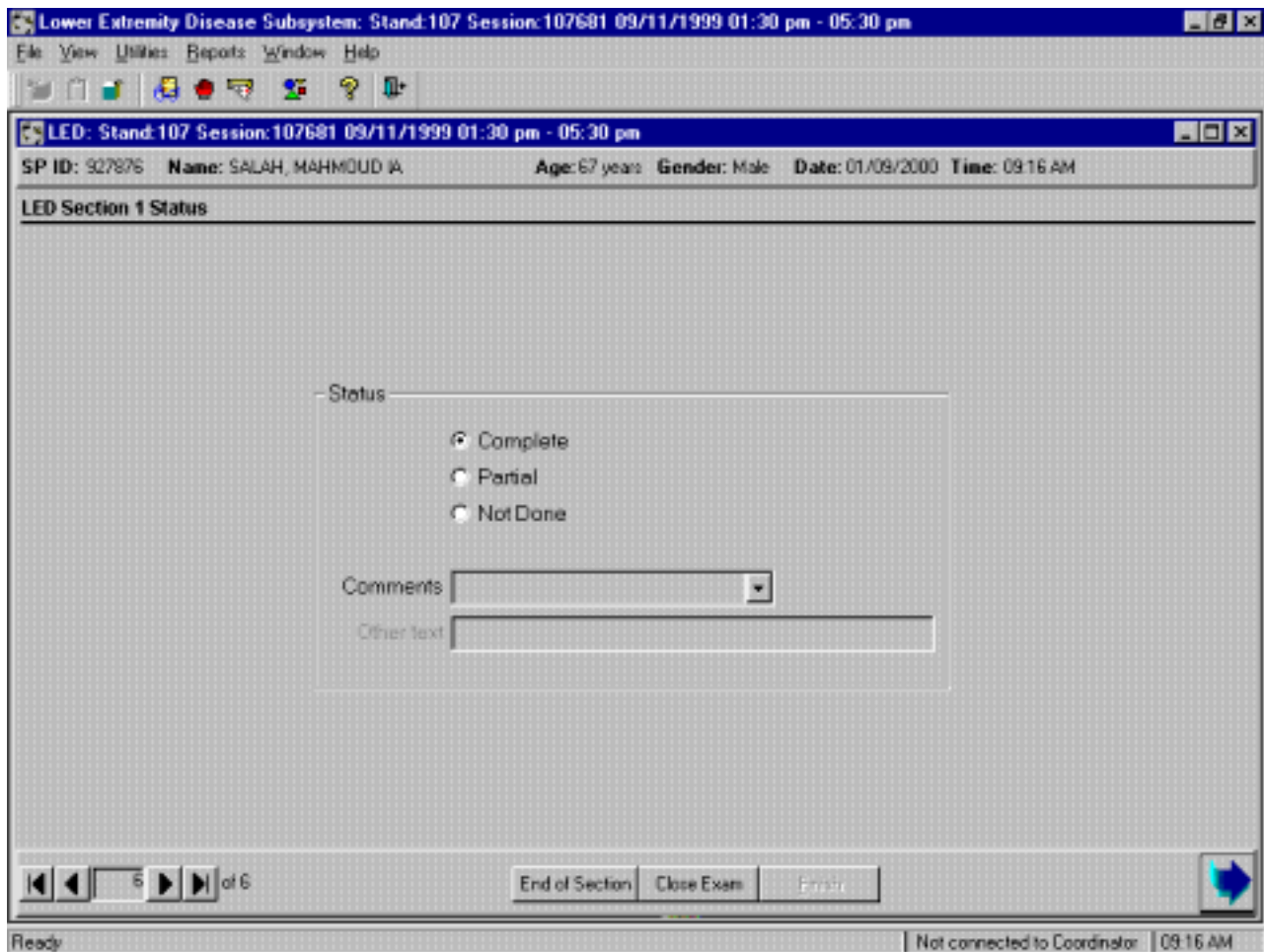
Exhibit 4-55. Peripheral neuropathy – Section 1 status screen



- The section status for the first section will default to “Partial.” Select “communication problem” from the drop down box and click the arrow at the bottom right hand side of the screen to get to Section 2.

4.5 End of Section One – Section Status Screen (Complete)

Exhibit 4-56. Status screen – Section 1



- If all the data have been collected for section one, the status for Section 1 will be 'complete.'

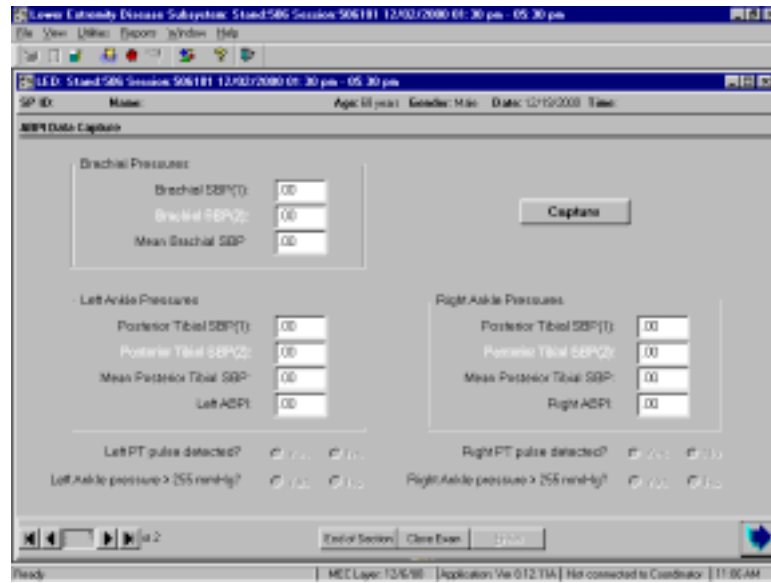
4.6 ABPI Data Capture

ABPI Data Capture Screens

Exhibit 4-57. ABPI data capture – SPs aged 40 - 59

- For SPs aged 40 - 59, systolic blood pressure (SBP) will be measured twice at all sites (brachial, right, and left posterior tibial).
- The system calculates and displays the mean of the two readings for all three sites.
- The system will calculate and display the ankle/brachial pressure index (ABPI) for the right and left ankles.
- If no blood pressures are captured at one or both of the ankles, the questions below the pressures will be enabled.

Exhibit 4-58. ABPI data capture – 60 years and above



- SPs 60 years of age and above will have pressures measured once only on each of the three sites (brachial, right, and left posterior tibial).
- The system will disable the fields for the second set of measurements.

Exhibit 4-59. ABPI data capture screen – right ankle pressure not captured

Category	Parameter	Value
Brachial Pressures	Brachial SBP(1)	145.00
	Brachial SBP(2)	00
	Mean Brachial SBP	145.00
Left Ankle Pressures	Posterior Tibial SBP(1)	97.00
	Posterior Tibial SBP(2)	00
	Mean Posterior Tibial SBP	97.00
	Left ADPI	1.15
Right Ankle Pressures	Posterior Tibial SBP(1)	00
	Posterior Tibial SBP(2)	00
	Mean Posterior Tibial SBP	00
	Right ADPI	00

- If there are no blood pressures captured at an ankle site, the question “Right PT pulse detected?” will be enabled. If the technician could not detect a pulse with the Doppler probe, the BP cuff will not be inflated, and no blood pressure will be obtained.
- If no pulse was detected, the technician will select “No” for this variable and the next question will not be enabled. The exam will be coded Complete.

Exhibit 4-60. ABPI data capture – right ankle pressure not captured, PT pulse detected

LEWIN: Extremity Disease Subsystem: Stand 586 Session 506181 12/02/2008 09:30 pm - 05:30 pm

LEWIN: Stand 586 Session 506181 12/02/2008 09:30 pm - 05:30 pm

SP ID: Name: Age: 63 years Gender: Male Date: 12/02/2008 Time:

ABPI Data Capture

Brachial Pressures:

Brachial SBP(T)	146.00
Brachial DBP(T)	00
Mean Brachial SBP	146.00

Left Ankle Pressures:

Posterior Tibial SBP(T)	97.00
Posterior Tibial DBP(T)	00
Mean Posterior Tibial SBP	97.00
Left ABI	1.15

Right Ankle Pressures:

Posterior Tibial SBP(T)	00
Posterior Tibial DBP(T)	00
Mean Posterior Tibial SBP	00
Right ABI	00

Left PT pulse detected? Yes No

Right PT pulse detected? Yes No

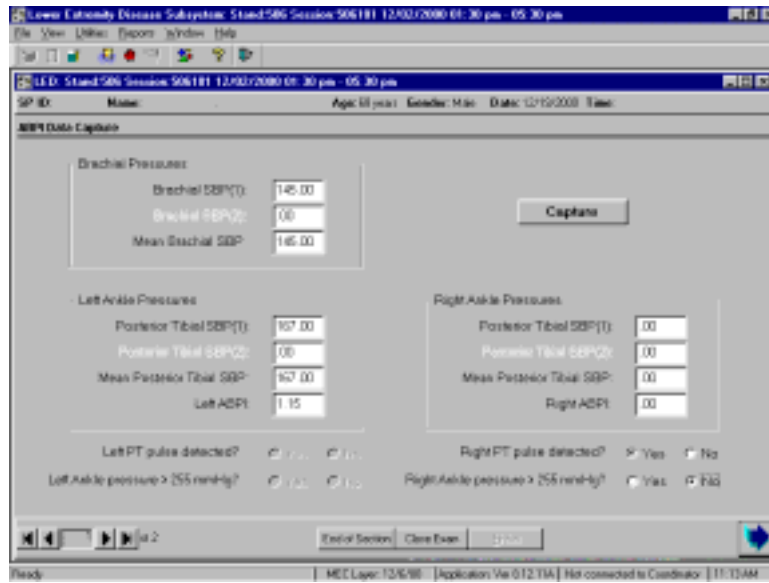
Left Ankle pressure > 255 mmHg? No Yes

Right Ankle pressure > 255 mmHg? Yes No

MEC Layer: 12/6/08 Application: Vse 012 TIA Not connected to Coordinator 11:12AM

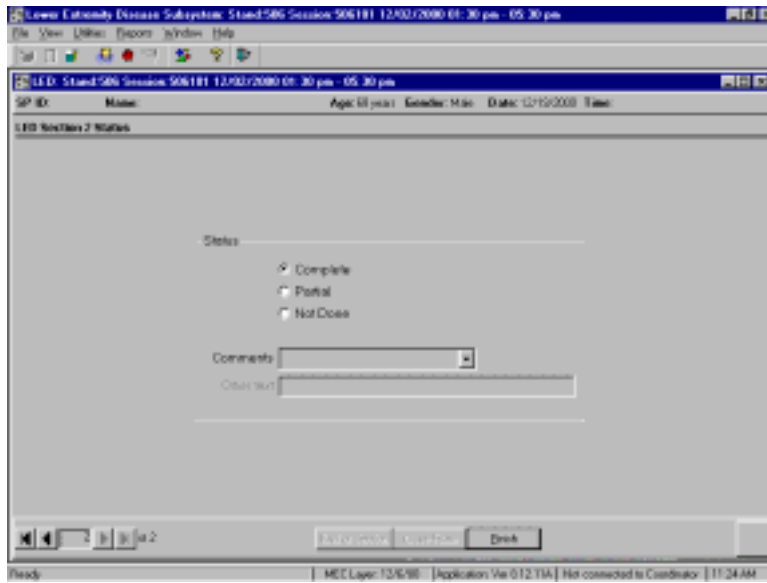
- If the answer to the pulse question is “Yes,” the question “Right Ankle pressure >255 mmHg?” will be enabled.

Exhibit 4-61. ABPI data capture – right ankle pressure not captured, ankle pressure less than 255 mmHg



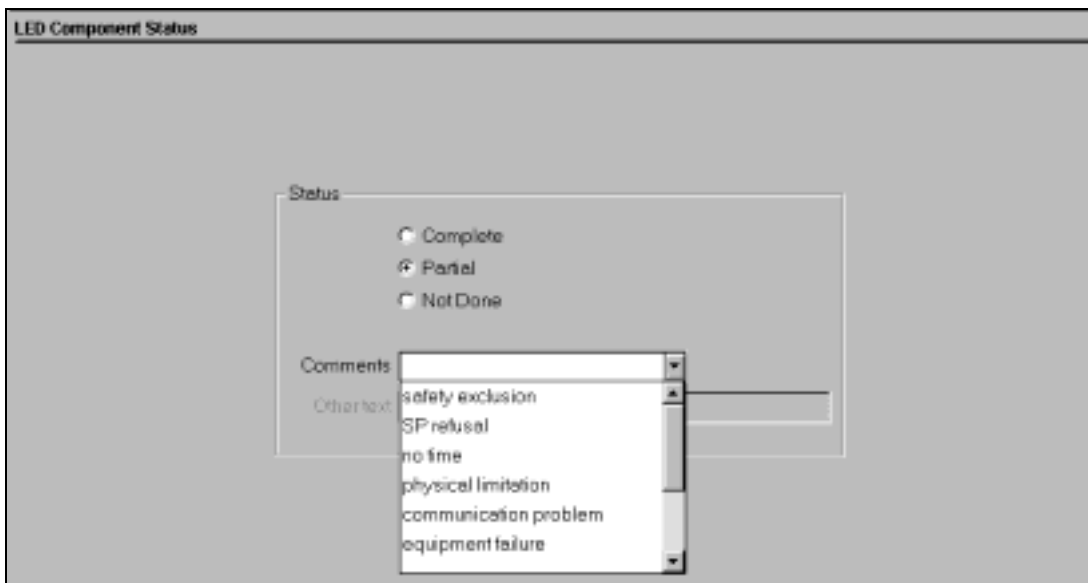
- If the ankle pressure was greater than 255 mmHg, (the inflation limit of the equipment), the answer to the question is “Yes,” and the exam is coded complete.
- If the ankle pressure is not greater than 255 mmHg, the answer to the question is “No,” and the exam is coded as a partial. The technician must enter a comment code for a partial exam.

Exhibit 4-62. ABPI Section Status screen



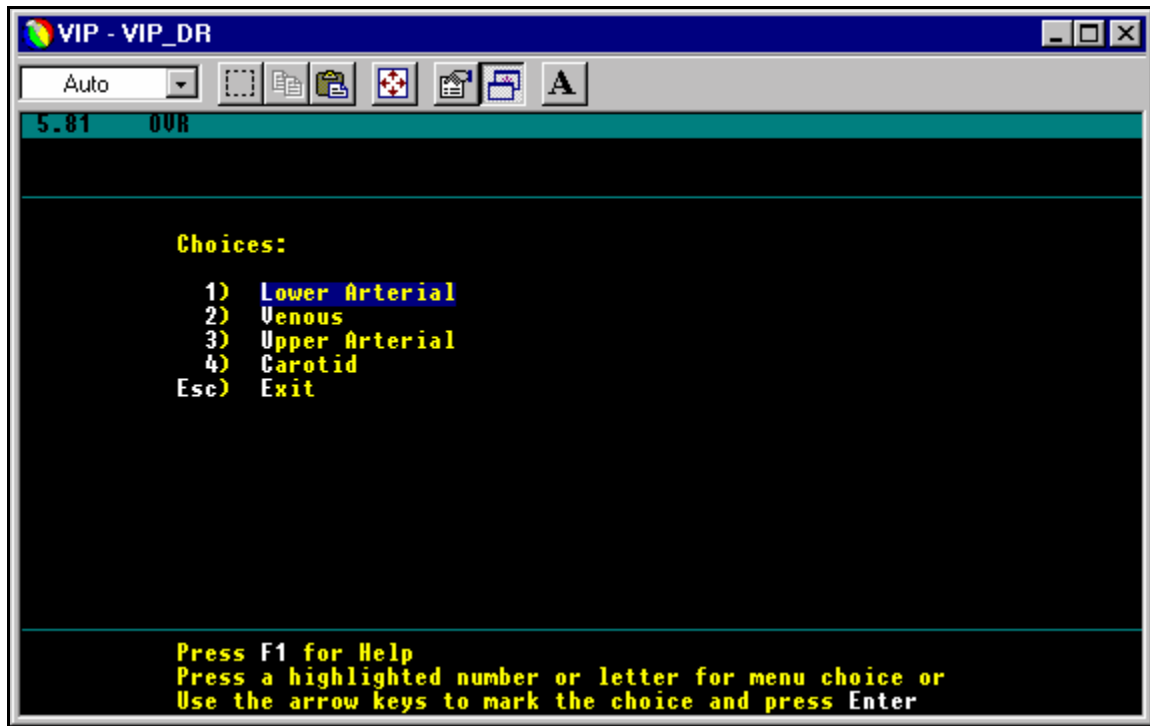
- If the Section Status is complete, no comment is required.
- A comment must be entered for a Partial or Not Done exam. See Exhibit 4-64 below.

Exhibit 4-63. LED exam status screen – Partial with comment required.



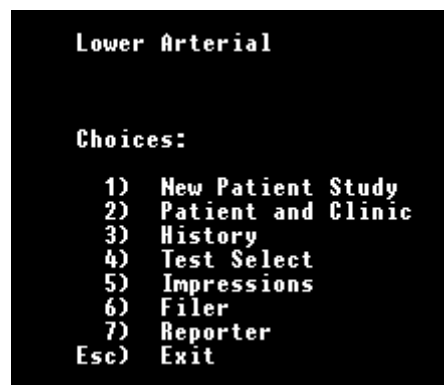
4.7 VIP BP Screens

Exhibit 4-64. VIP choices menu (1)



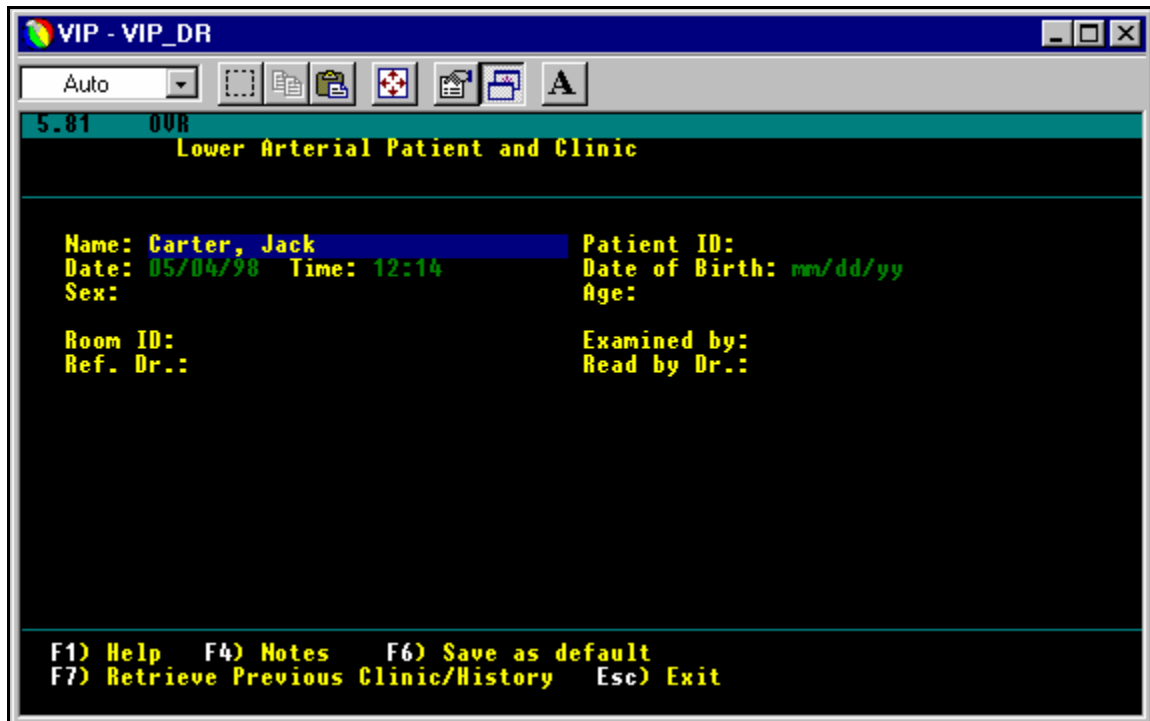
- When the system goes to the ABPI data capture screen, minimize the ISIS screen or Alt-Tab to the VIP software.
- Maximize the VIP application.
- The 'Choices' menu is the first screen.
- Type L for Lower Arterial.

Exhibit 4-65. VIP choices menu (2)



- Type N for New Patient Study.
- A message will appear on the bottom of the screen asking “Do you want to save the current study?”
- Type Y for Yes.

Exhibit 4-66. VIP ID entry screen



- A screen titled ‘Lower Arterial Patient and Clinic’ will appear.
- Type the SP’s ID in the Name field.
- Press the Escape key (Esc) to exit this screen.

Exhibit 4-67. VIP choices menu (3)

```
Lower Arterial

Choices:

1) New Patient Study
2) Patient and Clinic
3) History
4) Test Select
5) Impressions
6) Filer
7) Reporter
Esc) Exit
```

- A screen titled 'Lower Arterial' will appear.
- Press T for Test select.

Exhibit 4-68. VIP lower arterial test menu

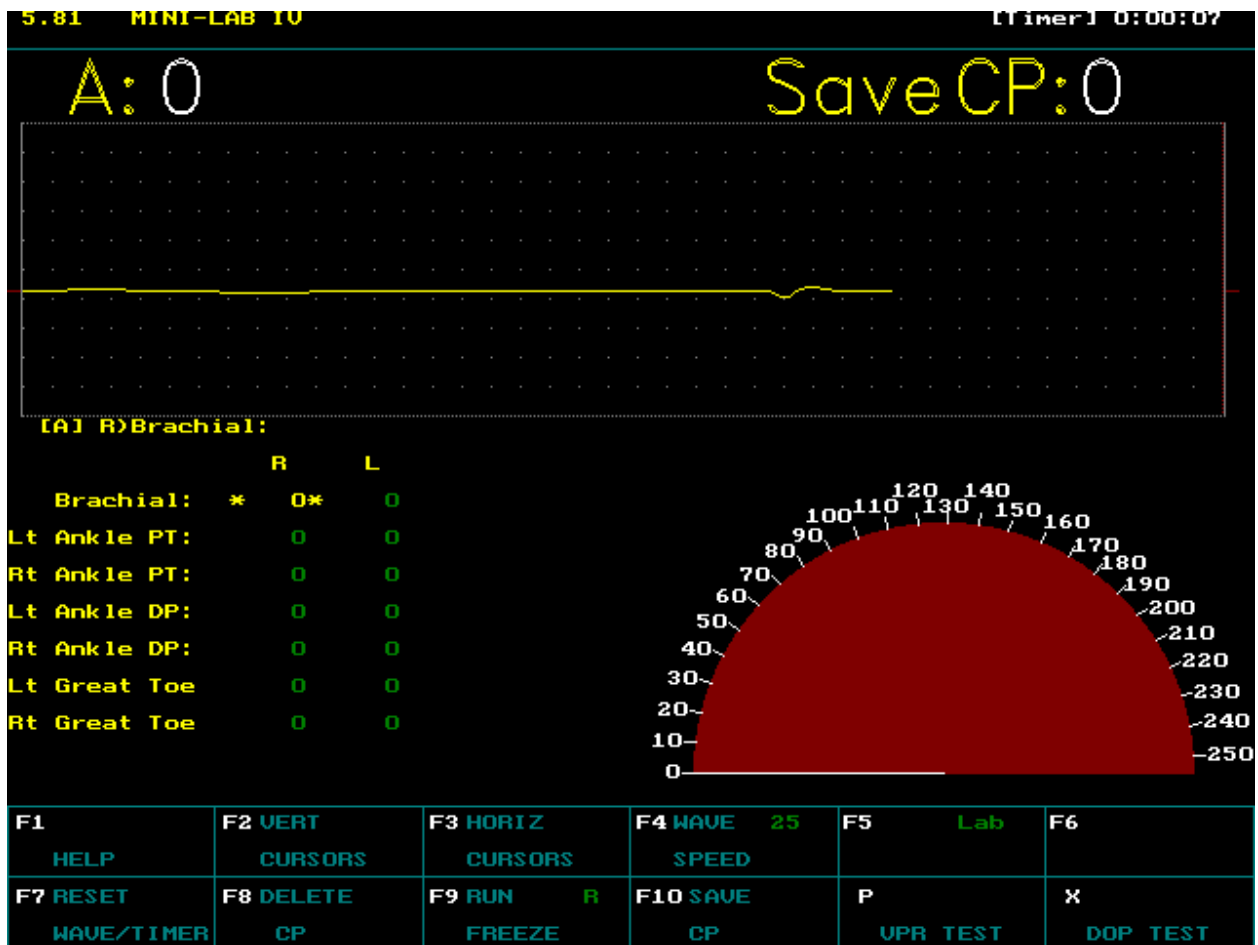
```
Lower Arterial Test

Choices:

1) Pulses
2) Doppler
3) V - Pulse Volume Recording
4) Segmental Limb Pressures
5) X - Exercise
6) Reactive Hyperemia
7) T - Pulse Reappearance Time
8) I - Penile
9) Lower Digits
Esc) Exit
```

- A screen titled 'Lower Arterial Test' (Choices) will appear.
- Press S for Segmental Limb Pressures.

Exhibit 4-69. VIP pressure measurement screen



- The Waveform Mode screen for pressure measurement will appear.
- The VIP software is ready to begin the pressure measurements.
- The cursor is on the Brachial measurement field.
- When the brachial measurement is taken, the cursor will move to the field for the left brachial measurement. This protocol does not enter the second brachial measurement in this field.
- Use the 'Down' and 'Left' arrow keys to move the cursor to the Left Posterior Tibial position.
- Once the cursor is in this position, it will advance automatically to the next site to be tested.
- When all the sites have been tested, press Escape (Esc).
- [You can press Esc three times to bypass the next three screens and get to the 'Lower Arterial (Choices)' menu.]

Exhibit 4-70. VIP lower arterial test segmental limb pressures

Lower Arterial Test Segmental Limb Pressures			
Right		Left	
Brachial:	140	Brachial:	136
Lt Ankle PT:	135 - 0.96	Lt Ankle PT:	132 - 0.94
Rt Ankle PT:	138 - 0.99	Rt Ankle PT:	142 - 1.01
Lt Ankle DP:	137 - 0.98	Lt Ankle DP:	134 - 0.96
Rt Ankle DP:	145 - 1.04	Rt Ankle DP:	140 - 1.00
Lt Great Toe:	123 - 0.88	Lt Great Toe:	118 - 0.84
Rt Great Toe:	115 - 0.82	Rt Great Toe:	112 - 0.80

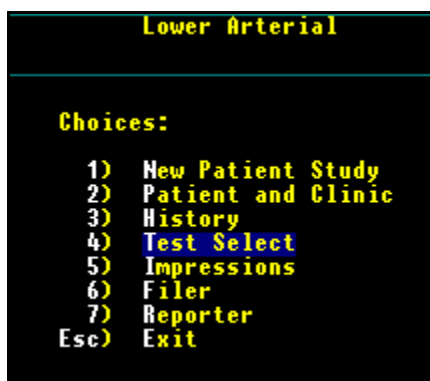
- The 'Lower Arterial Test Segmental Limb Pressures' screen appears.
- The pressures and the calculated indices are displayed. The indices calculated by the Parks software are slightly different from the indices that will be calculated by the ISIS.
- Press Escape (Esc) to exit from this screen.

Exhibit 4-71. VIP lower arterial test choices menu

Lower Arterial Test	
Choices:	
1)	Pulses
2)	Doppler
3)	U - Pulse Volume Recording
T 4)	Segmental Limb Pressures
5)	X - Exercise
6)	Reactive Hyperemia
7)	T - Pulse Reappearance Time
8)	I - Penile
9)	Lower Digits
Esc)	Exit

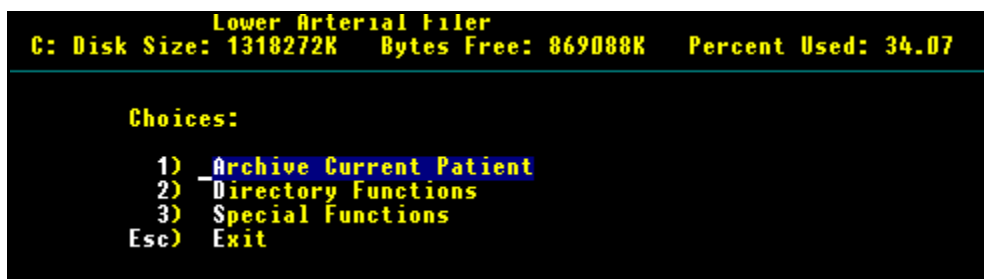
- The 'Lower Arterial Test' (Choices) screen appears.
- Press Escape (Esc) to exit from this screen.

Exhibit 4-72. VIP lower arterial choices menu



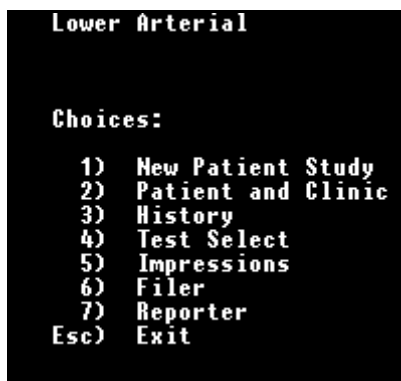
- The 'Lower Arterial (Choices)' screen appears.
- Press F for Filer.

Exhibit 4-73. VIP lower arterial filer



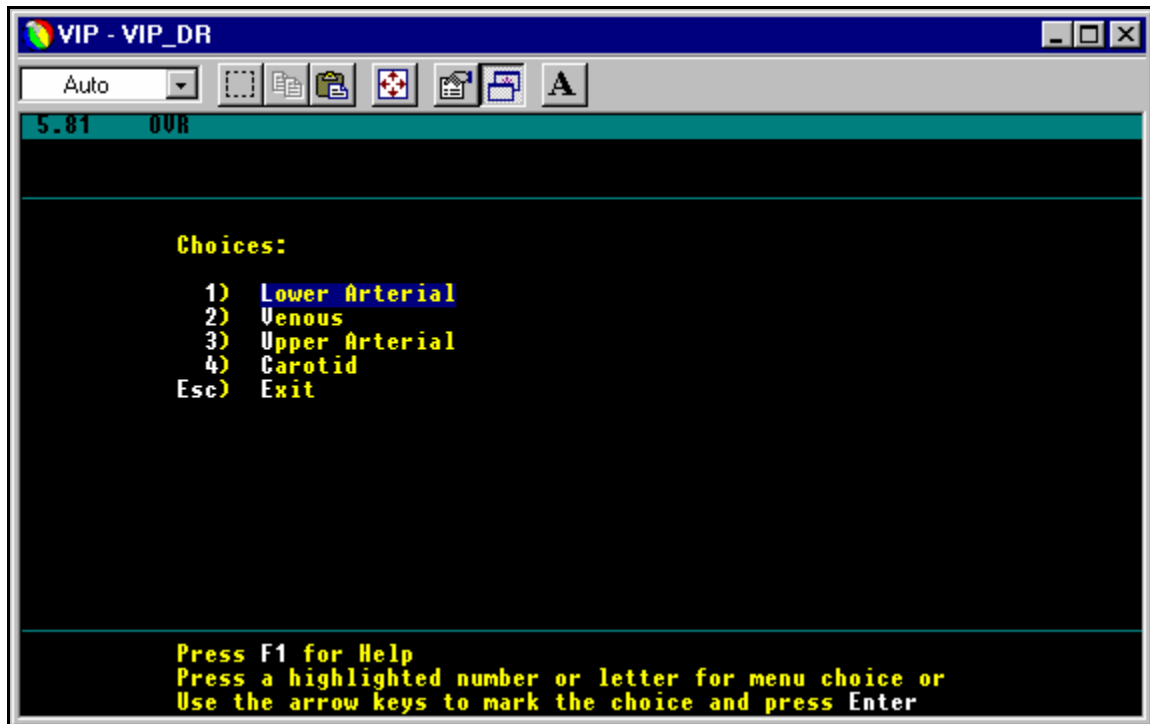
- The Lower Arterial Filer screen appears.
- Press A for Archive twice.
- Press Escape (Esc) to exit this screen.

Exhibit 4-74. VIP choices menu (3)



- The 'Lower Arterial' screen appears.
- Press Escape (Esc) to exit this screen.

Exhibit 4-75. VIP choices menu



- The first screen (Choices) appears again.
- If this is the end of the session and you want to close the VIP software:
 - Press E for Exit.
 - Type Y for Yes to the question "Are you sure?"
 - Maximize the ISIS application
- If you want to leave the VIP software running for the next exam:
 - Alt-Tab to return to the ISIS application

5. REFERRALS AND REPORT OF FINDINGS

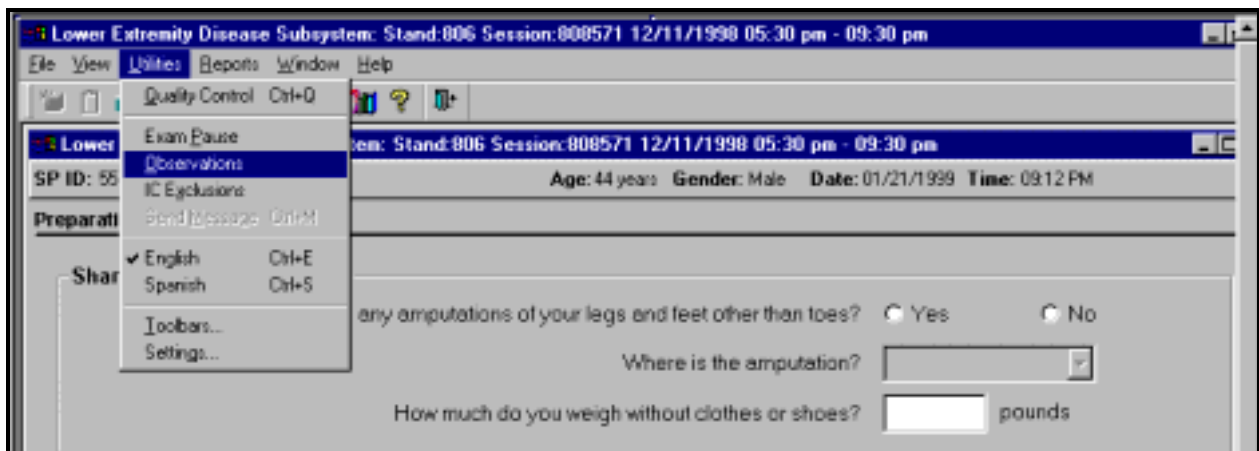
5.1 Observation Referrals

Observation referrals are nonemergency situations that may arise in any of the exam rooms in the MEC. Technicians 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.

The only standard criteria for sending an observation referral to the physician is if a SP has a brachial pressure of ≥ 210 mm Hg. If a technician obtains one arm blood pressure that is greater than or equal to 210, s/he must send an observation referral to the physician. The referral should read as follows: “Brachial SBP of at least 210 mm Hg was obtained in LED on [SP name].”

Once a technician sends a referral to the physician, the ISIS system will flag the referral for the SP in the Physician Referral Review Box. 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

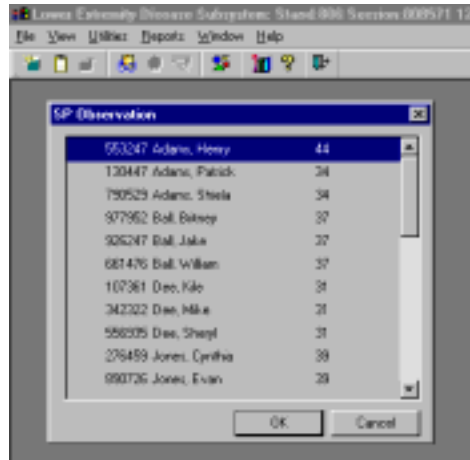


Observation Referrals can be sent during the exam or after the exam has been closed.

Under ‘Utilities’, select ‘Observations.’ If an exam is already opened, the Observation Referral box for that SP will be displayed. See Exhibit 5-3.

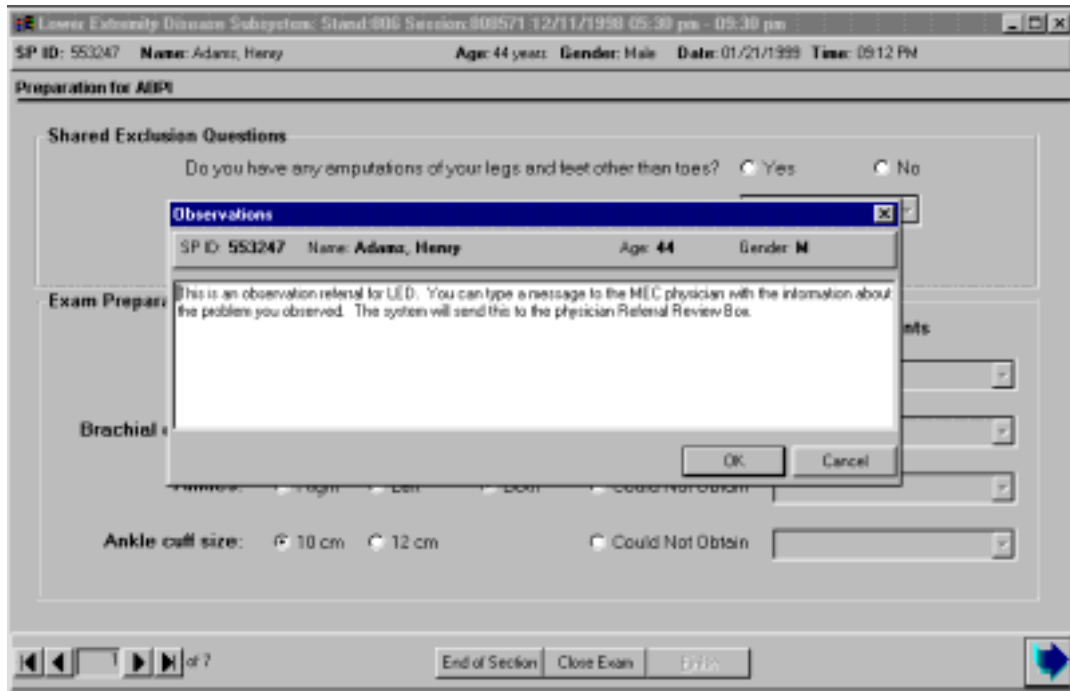
If the exam has been closed, select 'Observation' from the 'Utilities' menu. A pick list with the names of the SP's in the current session will be displayed. This list is only displayed if 'Utilities/Observations' is selected when an exam is not open. See Exhibit 5-2.

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



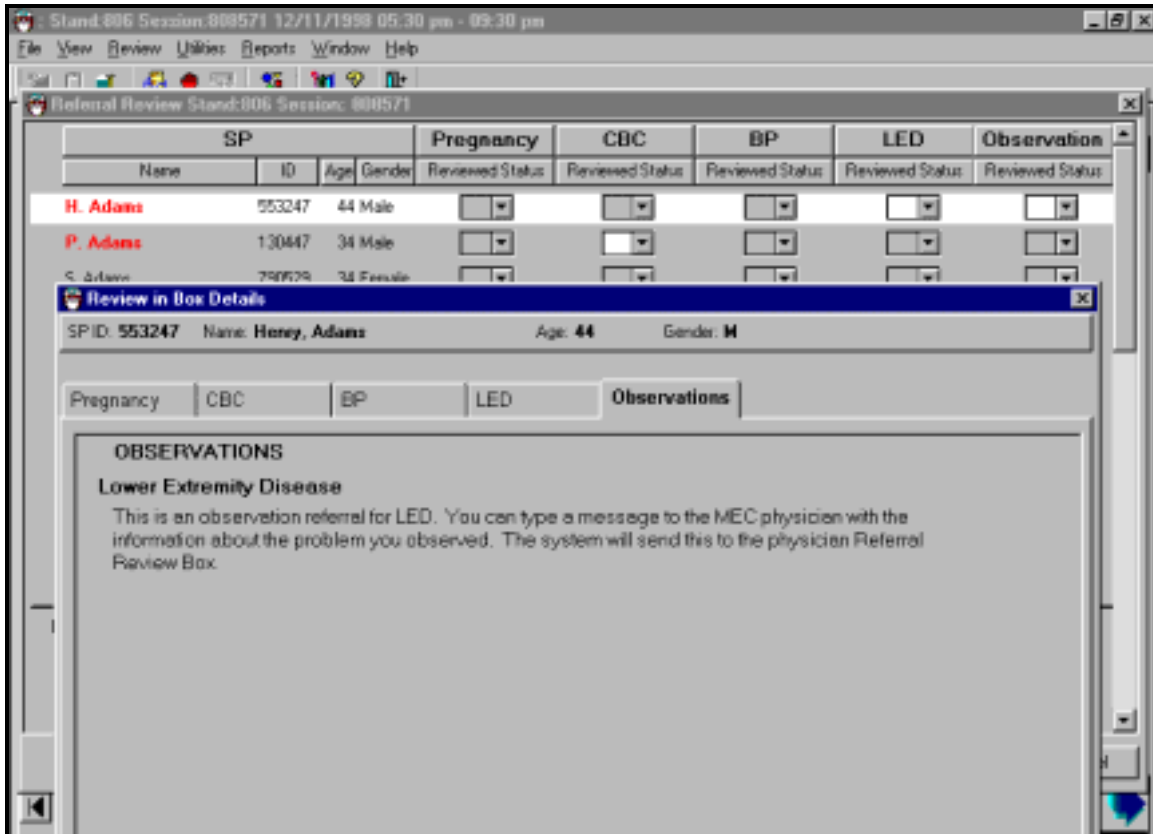
Select the name of the SP for whom an observation referral should be sent. Click OK.

Exhibit 5-3. Observation referral in LED



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

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



This is the referral as it appears in the physician's Referral Review box. The message typed in the Observation Referral box in LED 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 Data Related Referrals for LED

5.2.1 Definition of Referral Levels

Level 1 – Indicates major medical findings that warrant immediate attention by a health care provider. There will be no Level 1 referrals for any sections of the LED exam.

Level 2 – Indicates major medical findings that warrant attention by a health care provider within the next 2 weeks. These findings are expected to cause adverse effects within this time period and have previously been undiagnosed, unattended, not manifested, or not communicated to the participant by his/her personal health care provider.

The participant will be seen by the physician in the MEC (not to do an exam, but to generate the referral). The physician will get verbal consent from the examinee to contact his/her health care provider. A referral letter will then be generated to send to the health care provider. If the participant does not have a health care provider, the information will be sent to a referral medical facility with the consent of the participant. The referral letter will inform the health care provider about the results of the test and what the results mean.

Level 3 – Indicates minor medical findings that an examinee already knows about, is under care for, or does not require prompt medical attention. The results of the exam will be included in the report of findings with a brief explanation of the result.

5.2.2 Data Related Referrals for Peripheral Neuropathy

Some exams have data related referrals. These referrals are generated automatically by the system based on predefined referral edits. The lower extremity exam has data related referrals for both the monofilament test and for the ankle brachial pressure index.

Referral Criteria for Peripheral Neuropathy

The referral criteria for peripheral neuropathy is based on the cutaneous sensation at the tested sites. There is no Level 1 referral for peripheral neuropathy.

If number of insensate sites per foot is 1 or more, the system will send a Level 2 referral to the physician. This finding suggests decreased sensation in the affected foot, which places the SP at increased risk of foot abnormalities and problems.

This is a data related referral and will be automatically sent to the physician. The technician should not discuss the referral implications with the SP. All discussions about possible abnormalities should be referred to the physician.

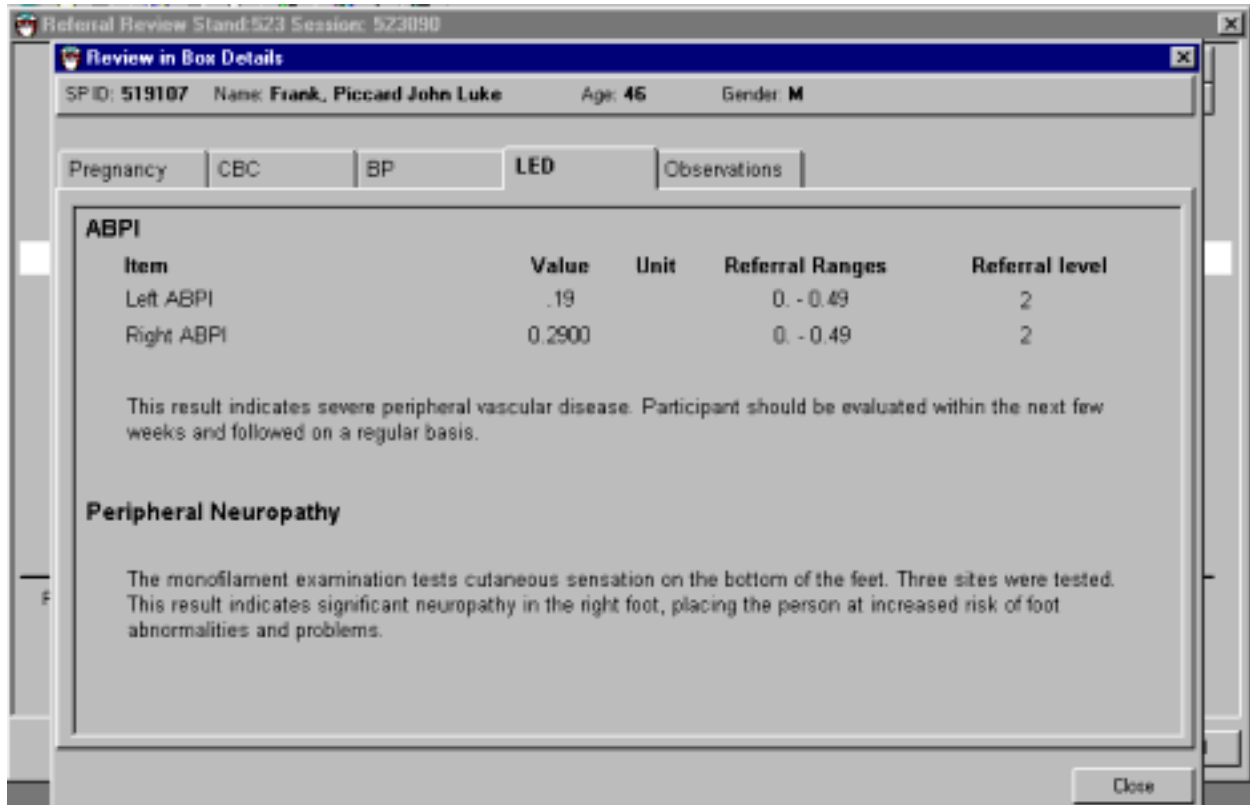
There is no Level 3 referral for peripheral neuropathy. If there are no insensate sites, the SP has normal sensation.

5.2.3 Definition of Sensate and Insensate for Referrals

Sensate (normal sensation) and insensate (decreased sensation) will be defined for referral purposes as follows:

- Correct – If first response to a site is ‘Correct,’ the test is not repeated on that site. This site would be defined as **sensate**.
- Incorrect – If first response is ‘Incorrect,’ the test must be repeated up to two times until a total of two similar responses are obtained. If two ‘Incorrect’ responses are obtained for a site, that site is considered **insensate**.
- Unable to Determine – If first response is ‘Unable to Determine,’ the test must be repeated up to two times until a total of two similar responses are obtained. If two ‘Unable to Determine’ responses are obtained for a site, that site is considered **insensate**.
- Incorrect or Unable to Determine – If first response is ‘Incorrect’ or ‘Unable to Determine,’ the test must be repeated up to two times until a total of two similar responses are obtained. Responses of ‘Incorrect’ on Test 1 and ‘Unable to Determine’ on Test 2 are considered two similar responses and that site would be defined as **insensate**.
- Could not Obtain – A response of ‘Could Not Obtain’ does not say anything about the sensation of that site.

Exhibit 5-5. Data related referrals for peripheral neuropathy



These referrals are generated automatically by the system and are sent to the Physician's Referral Review Box. SPs will not be checked out of the MEC until the physician has an opportunity to discuss the results of referrals with them.

5.2.4 Data Related Referrals for ABPI

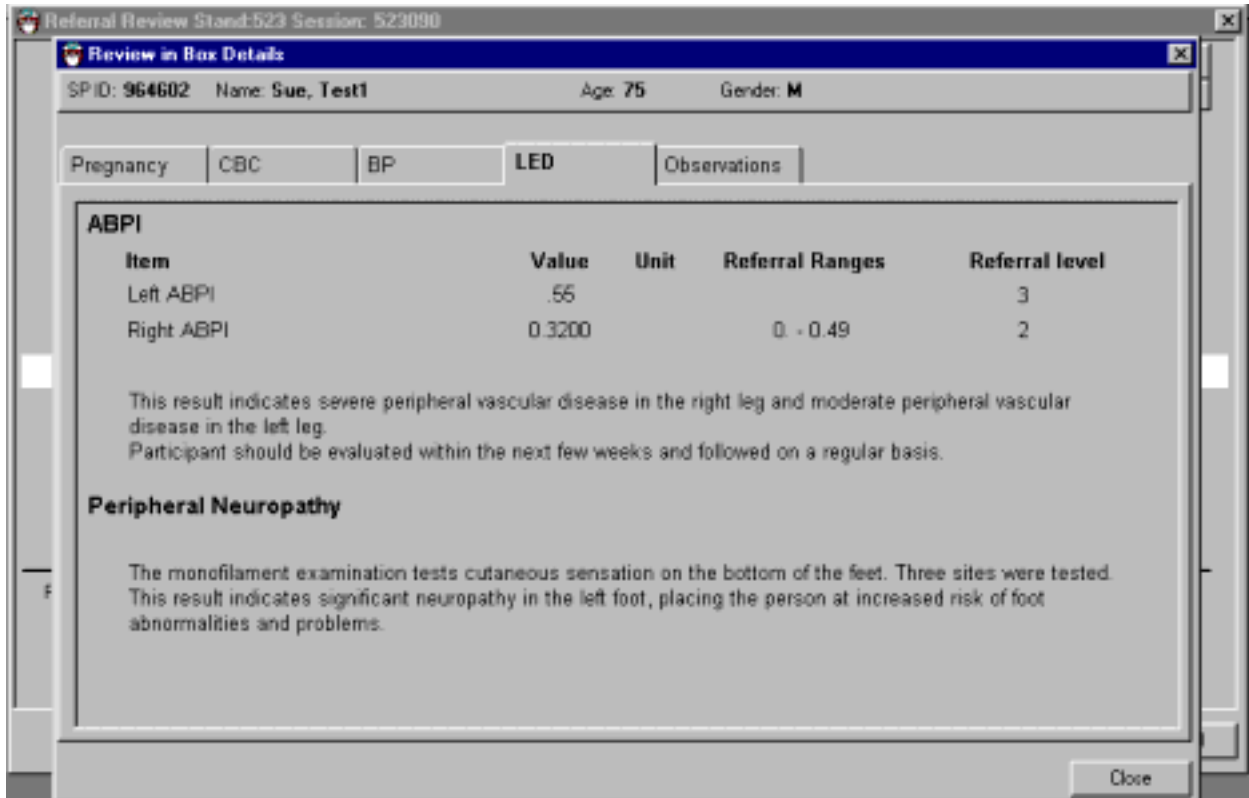
There are no Level 1 referrals for ABPI.

If the ABPI is less than 0.5, a Level 2 referral will be sent to the physician. This finding indicates severely decreased blood flow to the affected leg and the MEC physician will recommend that the SP see a health care provider in the next few weeks. This is a data related referral and will be automatically sent to the physician. The technician should not discuss the referral implications with the SP.

If the ABPI is 0.5 to 0.9, a Level 3 referral will be sent to the physician. This finding indicates moderately decreased blood flow to the affected leg. The MEC physician will discuss this with the SP and make a decision on what action if any should be taken.

An ABPI greater than 0.9 is considered normal.

Exhibit 5-6. Data related referrals for ABPI



These referrals are generated automatically by the system and are sent to the Physician's Referral Review Box. SPs will not be checked out of the MEC until the physician has an opportunity to discuss the results of referrals with them.

5.3 Report of Findings for Peripheral Neuropathy

Each SP will be given a report of the results or findings for the exams performed. The Report of Findings for the Lower Extremity Disease Exam will include a report on the monofilament test for peripheral neuropathy and on the ankle brachial pressure indices. The label for the monofilament test will be 'Foot Sensation' and a general statement will be given.

General statement: This sensory examination tests your ability to feel a filament pressed on the bottom of your feet. We tested three places on each foot. *Part A:* This examination showed that you have <normal, decreased> sensation <in your right foot, both feet>. *Part B:* and <normal, decreased> sensation in your left foot. *Part C:* We were not able to collect enough information to report results <on your right foot, on your left foot>.

If insensate areas per foot = 0, 'normal' will be printed in the statement.

If insensate areas per foot = 1 or more, 'decreased' will be printed in the statement.

If one of the legs has been amputated, the statement for that limb will be suppressed. If one or more sites on a foot were not able to be tested and received a 'Could Not Obtain' response, Part C of the above statement will be printed.

Example Situations:

If both right and left foot have same result, Part A will be printed and Part B and C will be suppressed.

Example: *"This sensory examination tests your ability to feel a filament pressed on the bottom of your feet. We tested three places on each foot. This examination showed that you have <normal, decreased> sensation in both feet."*

If right foot has one result and the left foot has a different result, Part A will be printed for the right foot and Part B will be printed for the left foot.

Example: *"This sensory examination tests your ability to feel a filament pressed on the bottom of your feet. We tested three places on each foot. This examination showed that you have <normal, decreased> sensation in your right foot and <normal, decreased> sensation in your left foot."*

If the left foot is amputated, the right foot will be reported as usual and the report for the left foot will be suppressed.

Example: *"This sensory examination tests your ability to feel a filament pressed on the bottom of your feet. We tested three places on each foot. This examination showed that you have <normal, decreased> sensation in your right foot."*

If the right foot is amputated, the left foot will be reported as usual and the report for the right foot will be suppressed.

Example: *“This sensory examination tests your ability to feel a filament pressed on the bottom of your feet. We tested three places on each foot. This examination showed that you have <normal, decreased> sensation in your left foot.”*

If Could Not Obtain is selected for one or more sites on a foot, the report for that foot will be suppressed and Part C will be printed.

Example: (Could Not Obtain for left hallux) – *“This sensory examination tests your ability to feel a filament pressed on the bottom of your feet. We tested three places on each foot. This examination showed that you have <normal, decreased> sensation in your right foot. ‘We were not able to collect enough information to report results on your left foot.’”*

Example: (Could Not Obtain for left hallux and Could Not Obtain for right metatarsal head)-
“We were not able to collect enough information to report results.”

5.4 Report of Findings for ABPI

General statement: *The blood pressure in your left ankle showed you have <normal, decreased, severely decreased> blood flow to your left leg and the blood pressure in your right ankle showed you have <normal, decreased, severely decreased> blood flow to your right leg.*

If one of the legs has been amputated, the statement for that limb will be suppressed.

Example Situations:

If both right and left ankle pressures are the same, the report will be reported as a combined statement for both legs.

Example: *“The blood pressure in both your ankles showed you have decreased blood flow to both legs.”*

If right ankle has one result and the left ankle has a different result, the results will be reported for each ankle.

Example: *“The blood pressure in your left ankle showed you have severely decreased blood flow to your left leg and the blood pressure in your right showed you have decreased blood flow to your right leg.”*

If the left foot is amputated, the right foot will be reported as usual and the report for the left foot will be suppressed.

Example: *“The blood pressure in your right ankle showed you have decreased blood flow to your right leg.”*

If the right foot is amputated, the left foot will be reported as usual and the report for the right foot will be suppressed.

Example: *“The blood pressure in your left ankle showed you have normal blood flow to your left leg.”*

6. QUALITY CONTROL

6.1 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; but 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.

6.1.1 Daily

Confirm the daily equipment checks are complete.

- Daily equipment checks:
 - Confirm Parks Mini-Lab power is on.
 - Confirm Output Filter is set to 3.5.
 - Confirm AC/DC/Reset toggle is set to AC.
 - Confirm sensitivity is set to 'Lo'.
 - Confirm PPG/VPR/Doppler toggle switch is set to 'Doppler'.
 - Confirm Remote Control is connected to Parks Mini-Lab.
 - Confirm 8.1 MHz Doppler probe is connected to Parks Mini-Lab.
 - Confirm headphones are connected to Parks Mini-Lab.

- Check calibration on Parks Mini-Lab with mercury manometer (0-70 mmHg within +/- 5 mmHg).
- Check calibration on Parks Mini-Lab with mercury manometer (70-120 mmHg within +/- 5 mmHg).
- Check calibration on Parks Mini-Lab with mercury manometer (120-180 mmHg within +/- 5 mmHg).
- Check calibration on Parks Mini-Lab with mercury manometer (180-220 mmHg within +/- 5 mmHg).
- Check calibration on Parks Mini-Lab with mercury manometer (220-255 mmHg within +/- 5 mmHg).

Confirm the daily room set-up procedures are complete.

- Daily room set-up procedures:
 - Change pillowcase after each exam session.
 - Wipe both sides of BP cuffs with disinfectant wipe after each SP exam.
 - Change exam table paper on stretcher after each SP exam.
 - Change disposable earphone covers after each SP exam.
- Check epoxy covering on Doppler probe for cracks or breaks.
 - Clean epoxy covering on Doppler probe with water (do not use alcohol).
 - Doppler probe should be clean and free from gel.
 - Do not allow gel to dry on epoxy covering.
- Clean monofilaments with alcohol (clean after each SP exam).
- Check headphone wires for cracks or breaks.

6.1.2 Weekly

- Complete all daily checks.
- Check Doppler remote for cracks.
- Check Doppler probe cord and connectors for cracks or breaks.
- Check Parks air pressure tubing and connectors for cracks and leaks.
- Check BP cuff tubing and connectors for cracks and leaks.

Check that calibration manometer is intact.

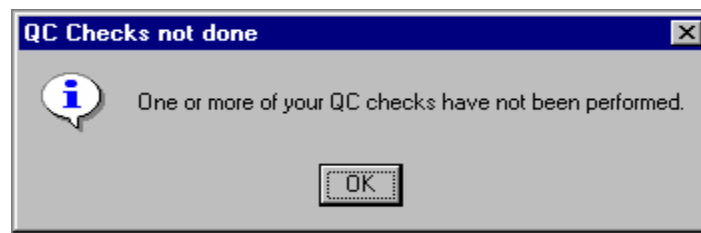
- Check that the level of mercury in glass is zero.
- Check that shape of meniscus is a smooth well-defined curve.
- Check that mercury rises easily in tubing and does not bounce noticeably when valve is closed.
- Check for cracks in glass tube.
- Check pressure control valve for sticks and leaks.
- Check V-Lok cuff for cracks or tears.

6.1.3 Stand

- Complete all daily checks.
- Complete all weekly checks.
- Wash BP cuff sleeves with soap and water.
- Replace pillow.

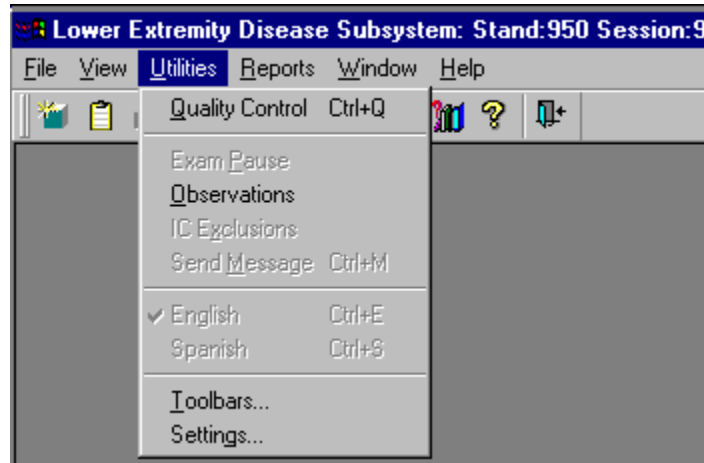
6.2 Data Entry Screens for QC on Equipment and Room Set-up

Exhibit 6-1. Quality Control reminder message box



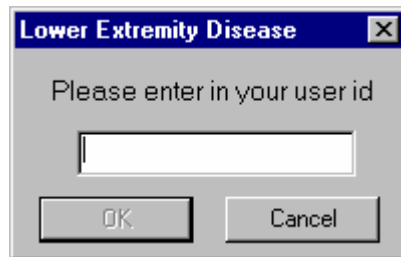
- When you log on to the application before the Quality Control checks are performed, the system displays a message: 'One or more of your QC checks have not been performed.'
- Click OK to this message and open the QC module and complete the listed checks.

Exhibit 6-2. Utilities menu to select Quality Control



- Selecting the Utilities menu can access the Quality Control screens. Select Quality Control from the menu.
- Clicking on the QC icon from the Toolbar can also access the QC screens.

Exhibit 6-3. User ID log on screen



- When QC is selected from the Utilities menu, the User ID entry box will be displayed.
- Each technician 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.

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

QC Check	Done	Result	Comment
Clean monitors with alcohol (clean after each use).	<input type="checkbox"/>		
Clean epoxy covering on Doppler probe with water (do not use alcohol)	<input type="checkbox"/>		
Check epoxy covering on Doppler probe for cracks or breaks.	<input type="checkbox"/>		
Confirm the daily room setup procedures are complete.	<input type="checkbox"/>		

- On the QC screens, check 'Done' for the listed items. 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 'Comments' field is used to enter information about problems encountered with the QC item check.
- Use the scroll bar to move to the remaining items. Click 'Done' for each item when the QC check is complete.

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

QC Check	Done	Result	Comment
Check BP cuff tubing and connectors for cracks and leaks.	<input type="checkbox"/>		
Check calibration on Parks Mini Lab with mercury manometer (0-70 mmHg within +/- 5mmHg).	<input type="checkbox"/>		
Check calibration on Parks Mini Lab with mercury manometer (70-120 mmHg within +/- 5mmHg).	<input type="checkbox"/>		

- Follow procedures for calibration checks as outlined in Section 2.4.
- If calibration checks are not within the acceptable range, enter the difference between the mercury manometer reading and the reading on the Parks VIP screen in the ‘Result’ field.
- Enter the reading on the manometer and the reading on the Parks VIP screen in the ‘Comments’ field.
- Notify the Chief Technologist. Make a note of this in the ‘Comments’ section.

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

QC Check	Done	Result	Comment
Check calibration on Parks Mini Lab with mercury manometer (120-180 mmHg within +/- 5mmHg).	<input checked="" type="checkbox"/>	Difference=10mm	Reading on Parks=162, VIP=172. Reported to MEC Manager.
Check calibration on Parks Mini Lab with mercury manometer (180-200 mmHg within +/- 5mmHg).	<input checked="" type="checkbox"/>	Difference=10mm	Reading on Parks=200, VIP=210. Reported to MEC Manager.
Check calibration on Parks Mini Lab with mercury manometer (220-255 mmHg within +/- 5mmHg).	<input checked="" type="checkbox"/>	Difference=10mm	Reading on Parks=238, VIP=248. Reported to MEC Manager.
Check calibration mercury manometer is intact	<input checked="" type="checkbox"/>		Glass is cracked. Reported to MEC Manager.

- Use the scroll bar to move to the remaining items. Click ‘Done’ for each item when the QC check is complete.

Exhibit 6-7. Quality Control weekly checks with comments

QC Check	Done	Result	Comment
Complete all daily checks.	<input type="checkbox"/>		
Check Doppler remote for cracks.	<input type="checkbox"/>		
Check Doppler probe cord and connectors for cracks or breaks.	<input type="checkbox"/>		
Check Parks air pressure tubing and connectors for cracks and leaks.	<input type="checkbox"/>		

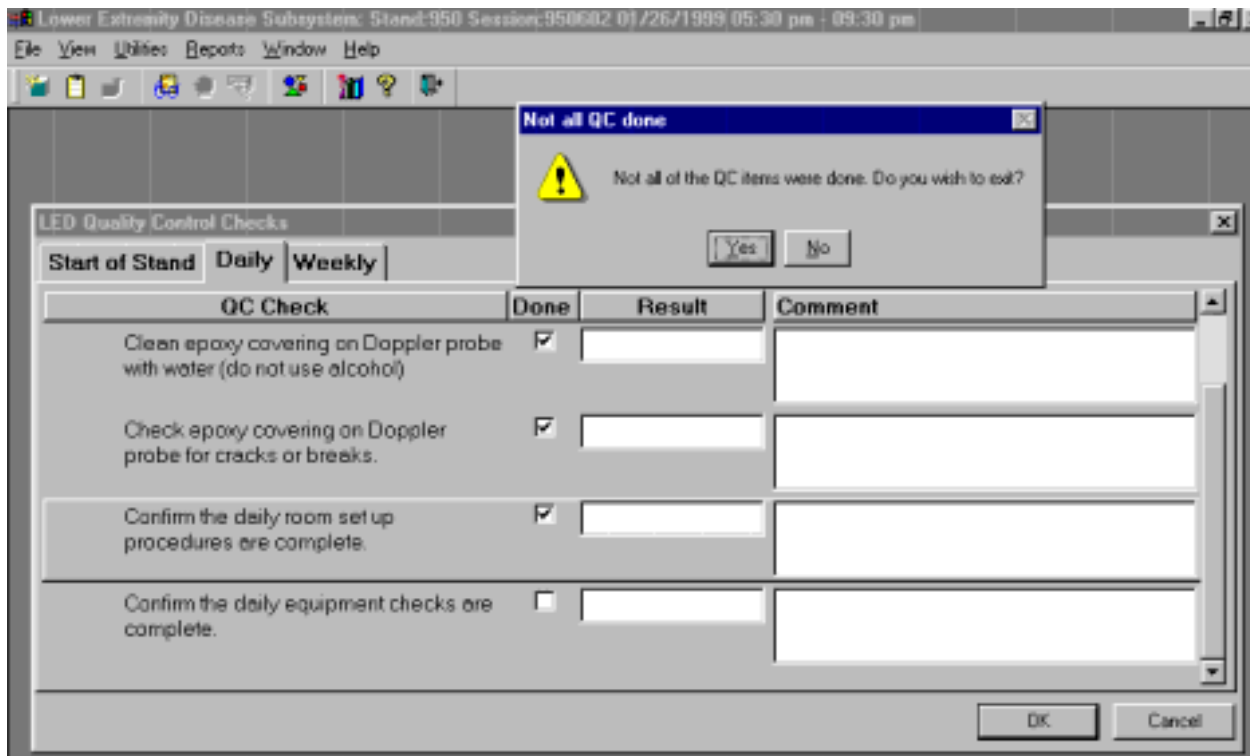
- Complete 'Weekly' checks.
- 'Weekly' checks include all daily checks.
- Use the scroll bar to move to the remaining items. Click 'Done' for each item when the QC check is complete.

Exhibit 6-8. Quality Control start of stand checks

QC Check	Done	Result	Comment
Complete all daily checks.	<input type="checkbox"/>		
Complete all weekly checks	<input type="checkbox"/>		
Wash BP cuff sleeves with soap and water	<input type="checkbox"/>		
Replace pillow	<input type="checkbox"/>		

- Complete 'Start of Stand' checks.
- 'Start of Stand' checks include all daily and weekly checks.

Exhibit 6-9. Quality Control incomplete entry



- 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?'
- If you want to complete the items before exiting, click No to this message and complete the items.
- If you do wish to exit without completing all QC item 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.

APPENDIX A. STANDARD SCRIPTS AND EXPLANATION OF EXAM PROCEDURES

ENGLISH VERSION

Component Introduction (This is not a Standard Script)

“In this room I am going to do several tests to measure the pressures in your arm and ankles. I’ll explain the test in more detail as we go through the test. First I am going to check the circumference of your arm in order to fit you with the correct blood pressure cuff. After I obtain the correct cuff size, I will ask you to lie down on the table and get as comfortable as possible, and I will put blood pressure cuffs on your arm and ankles. The purpose of this set of tests is to give us some information about peripheral vascular disease or disease that affects the blood vessels in the lower legs and ankles. This disease occurs in some people as they get older and particularly in diabetics.”

Explanation of Monofilament Test (Standard Script)

“Before I take the pressures, I want to test the sensation or sense of touch on the bottom of your feet. To do this test, I will use this small filament to apply pressure to different spots on your foot. It is not sharp and will not break the skin.”

Technician will show the SP the filament and touch the SP’s arm with the filament so the SP will know what to expect.

“As I apply the pressure I will be saying ‘A, B’ and I will be applying the pressure either as I am saying ‘A’ or as I am saying ‘B’. I want you to tell me whether you felt the pressure when I said ‘A’ or when I said ‘B’. Let me demonstrate on your arm.”

Demonstrate the procedure on the SP’s arm. Be sure the SP understands the test before starting. Repeat the explanation if necessary.

“Do you understand?”

Explanation of the Doppler

“I will be using this instrument called a Doppler to measure your blood pressures, rather than a stethoscope that is usually used to take blood pressure in a physician’s office. I will be wearing headphones to hear the Doppler sounds and to block out any extra noises. Do you have any questions before I begin?”

SPANISH VERSION**Component introduction (Not a standard script)**

“En este cuarto voy a hacer varias pruebas para medirle la presión de los brazos y de los tobillos. Le explicaré la prueba con más detalle mientras hacemos la prueba. Primero voy a verificar la circunferencia de su brazo para poder escoger la banda correcta que mide la presión sanguínea. Después de que obtenga el tamaño correcto de la banda, le pediré que se acueste sobre la mesa y se ponga lo más cómodo(a) posible, y le pondré las bandas para medirle la presión sanguínea en los brazos y en los tobillos. El propósito de este conjunto de pruebas es obtener alguna información acerca de cualquier enfermedad vascular periférica o enfermedad que afecte los vasos sanguíneos en la parte inferior de las piernas y en los tobillos. Esta enfermedad se produce en algunas personas cuando envejecen, particularmente en los diabéticos.”

Explanation of Peripheral Neuropathy (Standard Script)

"Antes de que le tome las presiones, quiero hacerle una prueba de la sensación o sentido del tacto en la planta de los pies. Para hacerle esta prueba, usaré este pequeño filamento para aplicar presión en diferentes puntos del pie. No es punzante y no le romperá la piel.

(Technician will show the SP the filament and touch the SP's arm with it so the SP will know what to expect).

Mientras aplico la presión diré "A, B" y aplicaré la presión ya sea cuando esté diciendo "A" o cuando esté diciendo "B". Quiero que usted me diga si sintió la presión cuando yo dije "A" o cuando dije "B". Déjeme hacerle una demostración en el brazo."

(Demonstrate the procedure on the SP's arm. Be sure the SP understands the test before starting. Repeat the explanation if necessary).

"¿Comprende?"

Explanation of the Doppler

“Voy a usar este instrumento, que se llama “Doppler,” para medir su presión sanguínea en vez de un estetoscopio que normalmente se usa en un consultorio médico para medir la presión sanguínea. Voy a usar audífonos para oír los sonidos del “Doppler” y para no oír otros sonidos. ¿Tiene usted alguna pregunta antes de empezar?”

APPENDIX B. VIP SEQUENCE FOR LED EXAM

Begin exam:

- Type L for Lower Arterial.
- Type N for New Patient.
- Y to save previous data.
- Enter SP ID.
- Press Escape.
- Type T for Test Select.
- Type S for Segmental.

End exam:

- Press Escape three times on VIP.
- Press F for Filer.
- Press Archive twice.
- Press Escape twice to return to first VIP screen.

APPENDIX C. DATA ENTRY SCREENS

Lower Extremity Disease Subsystem: Stand:506 Session:506211 12/05/2000 01:30 pm - 05:30 pm

File View Utilities Reports Window Help

LED: Stand:506 Session:506211 12/05/2000 01:30 pm - 05:30 pm

SP ID: 196924 Name: SILLARD2, MARY Age: 40 years Gender: Female Date: 12/05/2000 Time: 02:24 PM

Preparation for ABPI

Shared Exclusion Questions

Do you have any amputations of your legs and feet other than toes? Yes No

Where is the amputation?

How much do you weigh without clothes or shoes? pounds

Exam Preparation

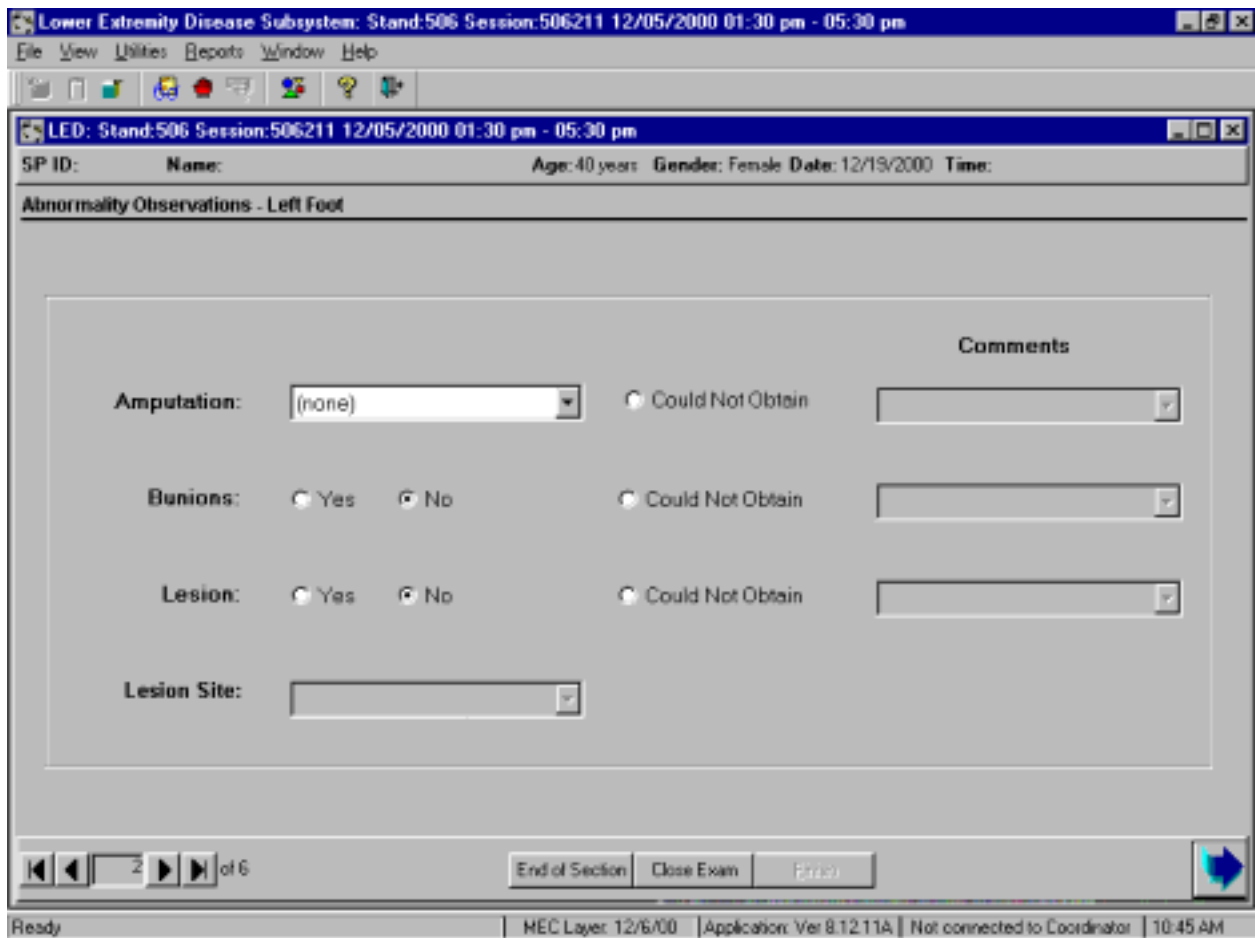
Arm:	<input checked="" type="radio"/> Right <input type="radio"/> Left	<input type="radio"/> Could Not Obtain	<input type="text"/>
Arm Cuff Size:	<input type="radio"/> Child <input type="radio"/> Adult <input type="radio"/> Large Adult <input type="radio"/> Thigh	<input type="radio"/> Could Not Obtain	<input type="text"/>
	Large adult selected due to poor thigh cuff fit?	<input type="radio"/> Yes <input type="radio"/> No	
Ankles:	<input type="radio"/> Right <input type="radio"/> Left <input checked="" type="radio"/> Both	<input type="radio"/> Could Not Obtain	<input type="text"/>
Ankle Cuff Size:	<input type="radio"/> Child <input type="radio"/> Adult <input type="radio"/> Large Adult	<input type="radio"/> Could Not Obtain	<input type="text"/>

1 of 6

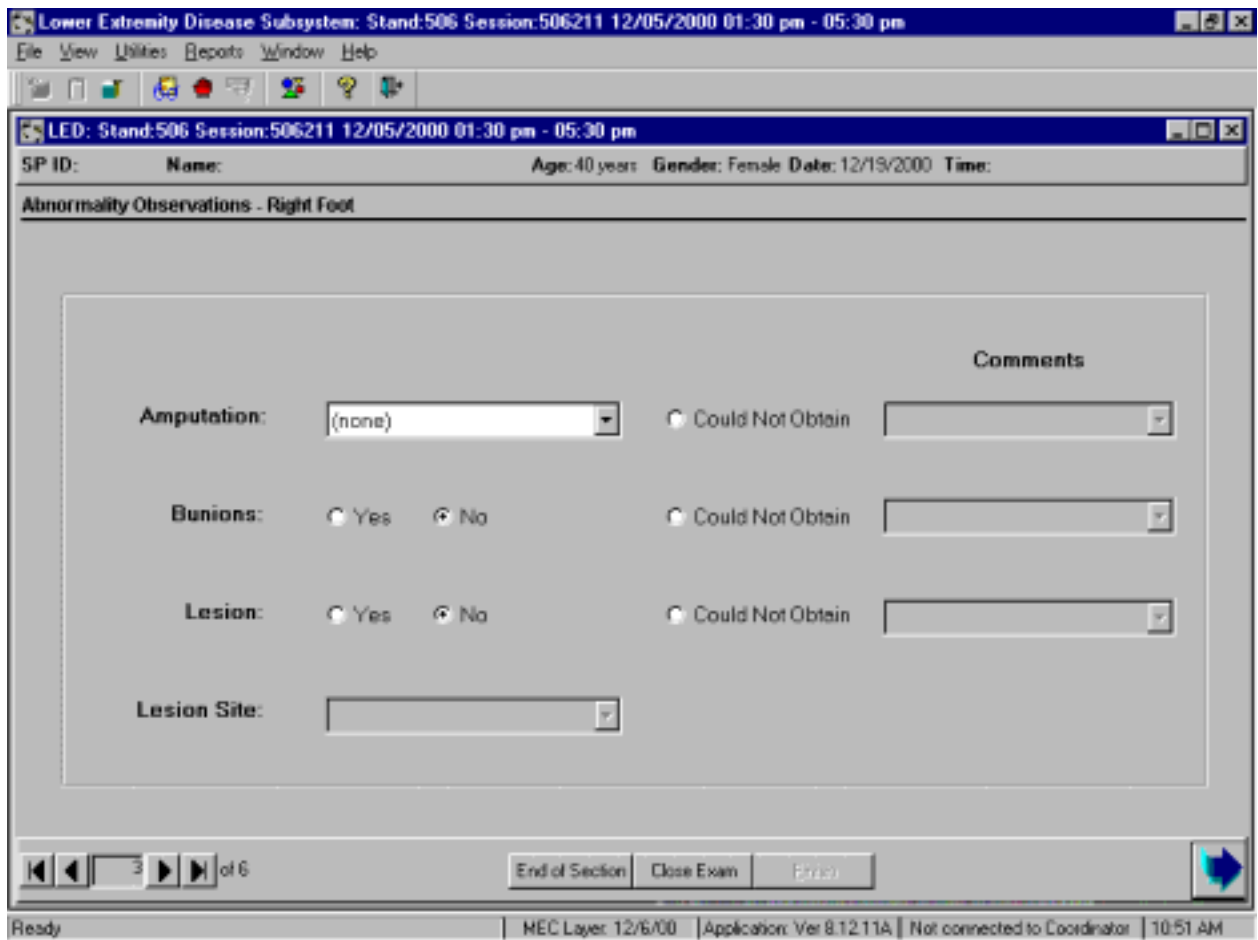
End of Section Close Exam Print

Ready | MEC Layer: 11/15/00 | Application: Ver 8.12.6A | Not connected to Coordinator | 02:24 PM

Screen 1: ABPI Preparation screen



Screen 2: Abnormality Observations - Left Foot



Screen 3: Abnormality Observations - Right foot


Lower Extremity Disease Subsystem: Stand:506 Session:506211 12/05/2000 01:30 pm - 05:30 pm

File View Utilities Reports Window Help

LED: Stand:506 Session:506211 12/05/2000 01:30 pm - 05:30 pm

SP ID: Name: Age: 40 years Gender: Female Date: 12/19/2000 Time:

Peripheral Neuropathy - Left Foot



	Correct	Incorrect	Unable to Determine	Could not Obtain	Comments
1st Test					
Metatarsal head 1	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Hellux	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Metatarsal head 5	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
2nd Test					
Metatarsal head 1	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Hellux	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Metatarsal head 5	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
3rd Test					
Metatarsal head 1	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Hellux	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Metatarsal head 5	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	

4 of 6

End of Section Close Exam Error

Ready | MEC Layer: 12/6/00 | Application: Ver 8.12.11A | Not connected to Coordinator | 10:51 AM

Screen 4: Peripheral Neuropathy - Left foot

Lower Extremity Disease Subsystem: Stand:506 Session:506211 12/05/2000 01:30 pm - 05:30 pm

File View Utilities Reports Window Help

LED: Stand:506 Session:506211 12/05/2000 01:30 pm - 05:30 pm

SP ID: Name: Age: 40 years Gender: Female Date: 12/19/2000 Time:

Peripheral Neuropathy - Right Foot

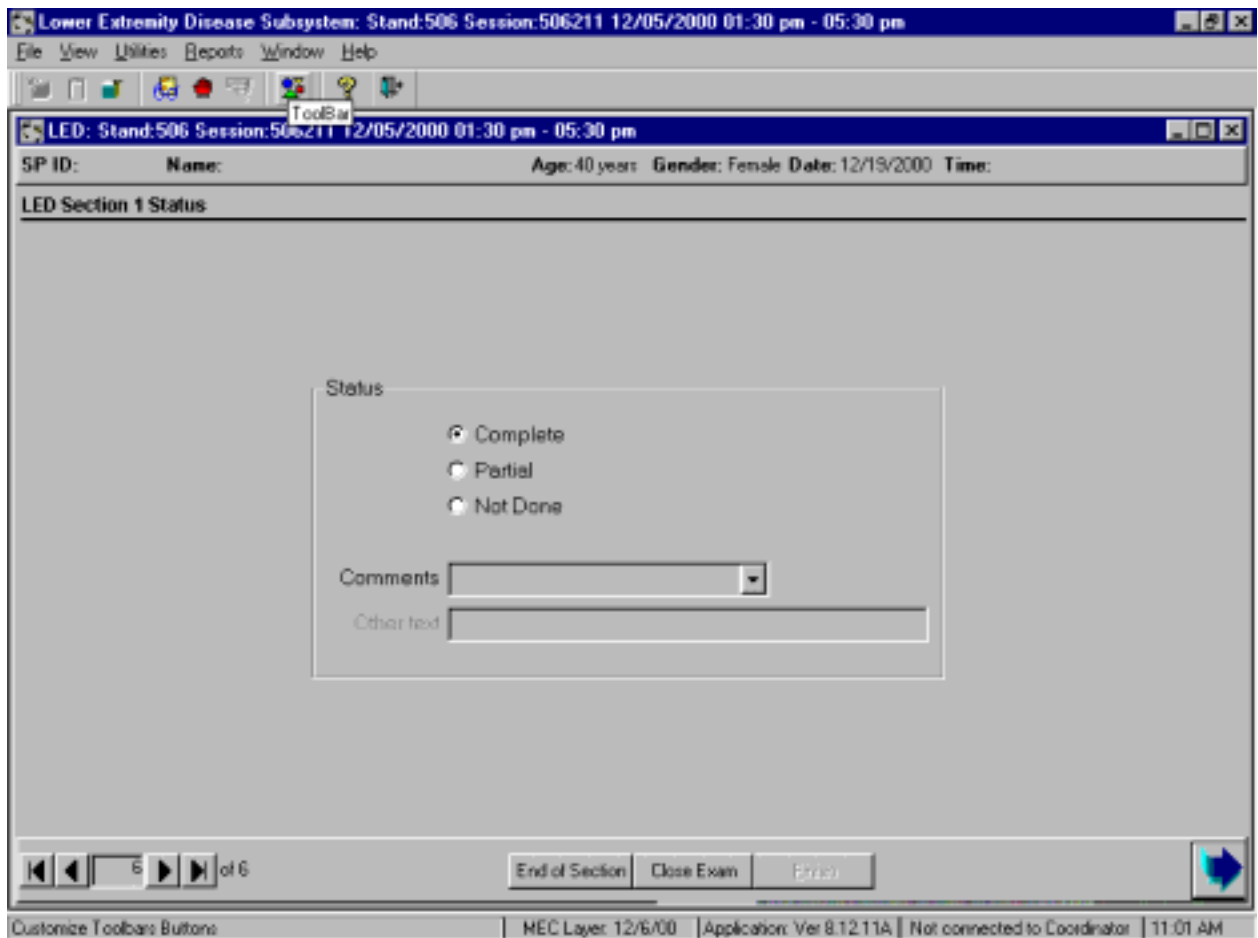
	Correct	Incorrect	Unable to Determine	Could not Obtain	Comments
1st Test					
Hallux	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Metatarsal head 1	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Metatarsal head 5	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
2nd Test					
Hallux	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Metatarsal head 1	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Metatarsal head 5	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
3rd Test					
Hallux	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Metatarsal head 1	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Metatarsal head 5	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	

5 of 6

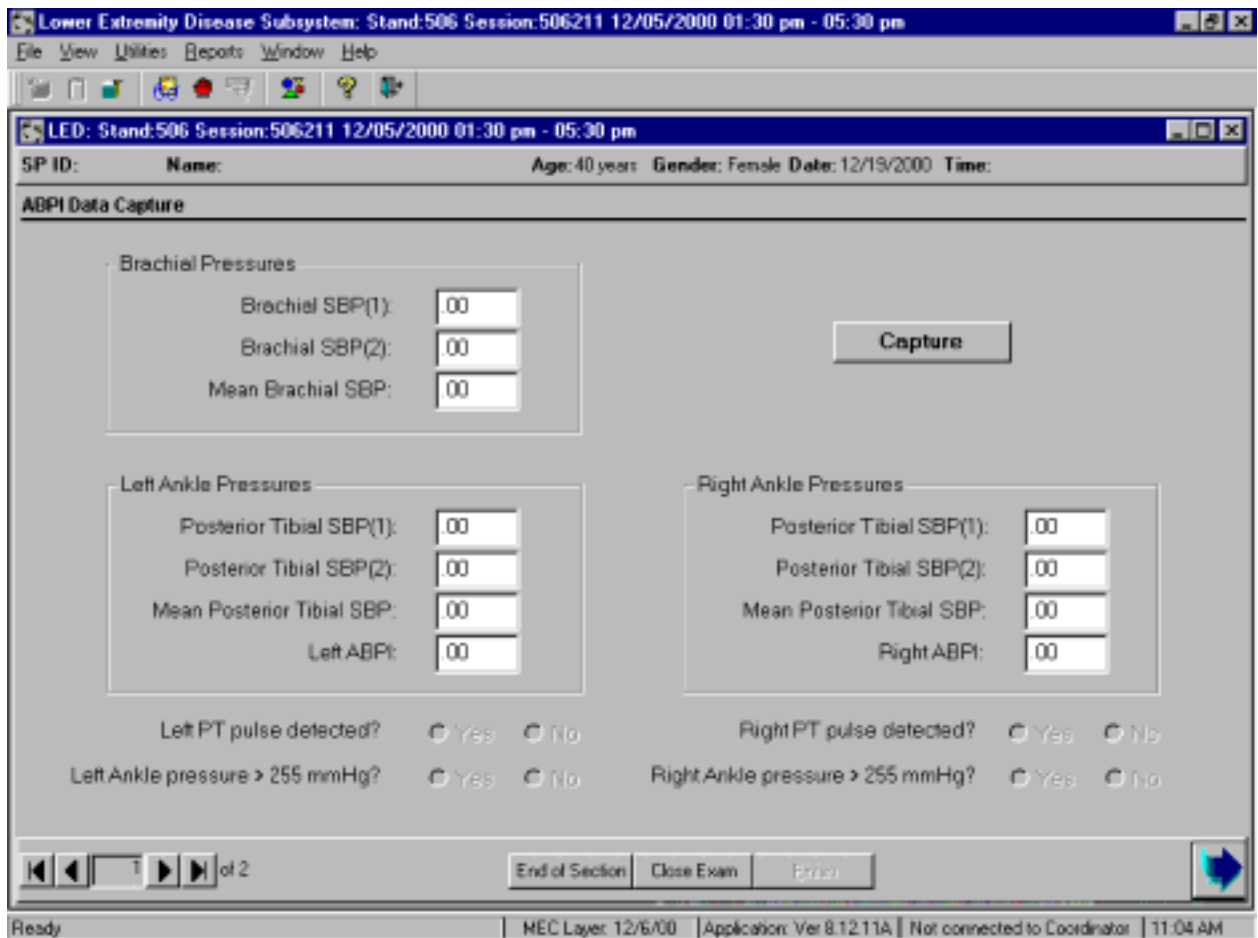
End of Section Close Exam Exit

Ready | MEC Layer: 12/6/00 | Application: Ver 8.12.11A | Not connected to Coordinator | 11:00 AM

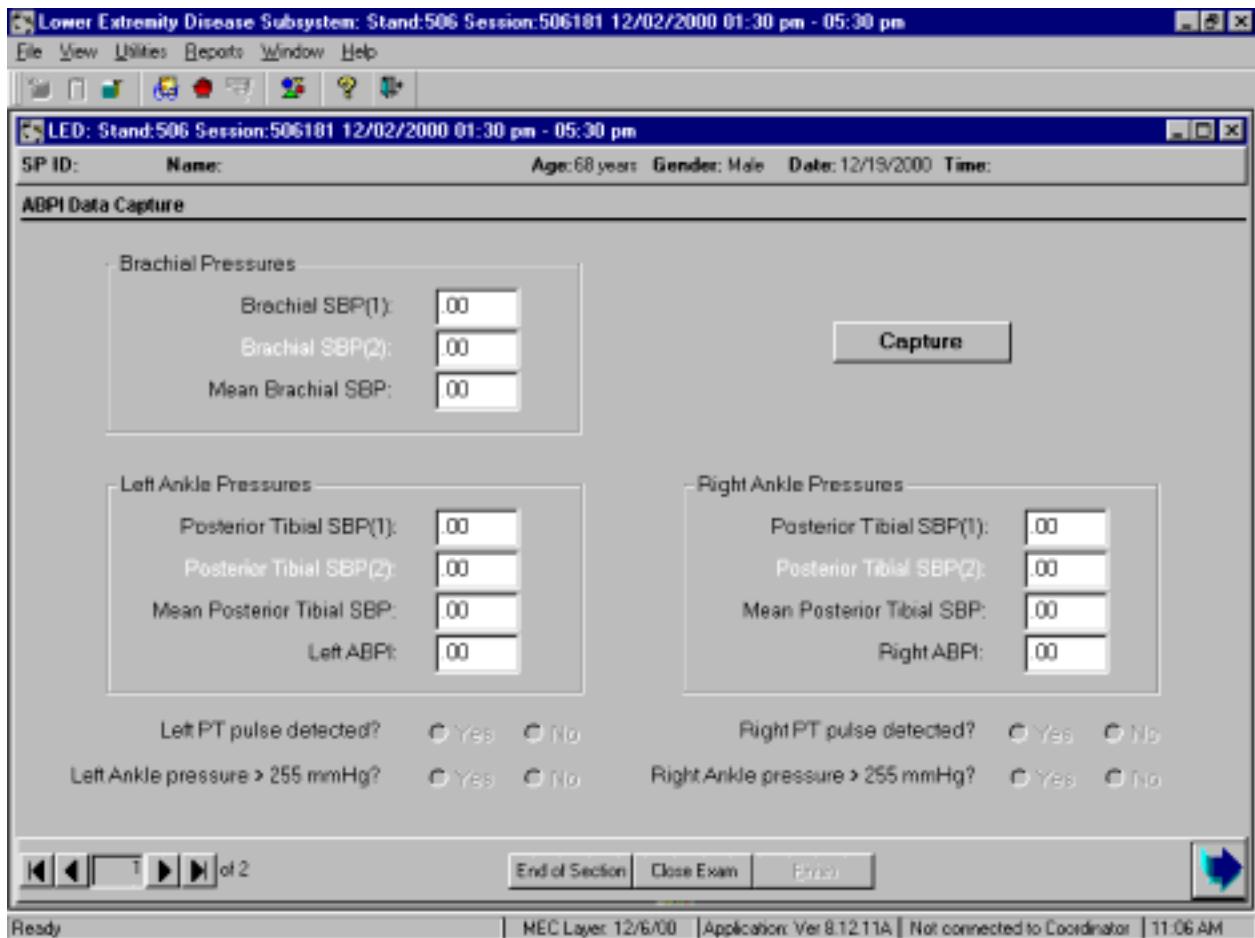
Screen 5: Peripheral Neuropathy Left Foot



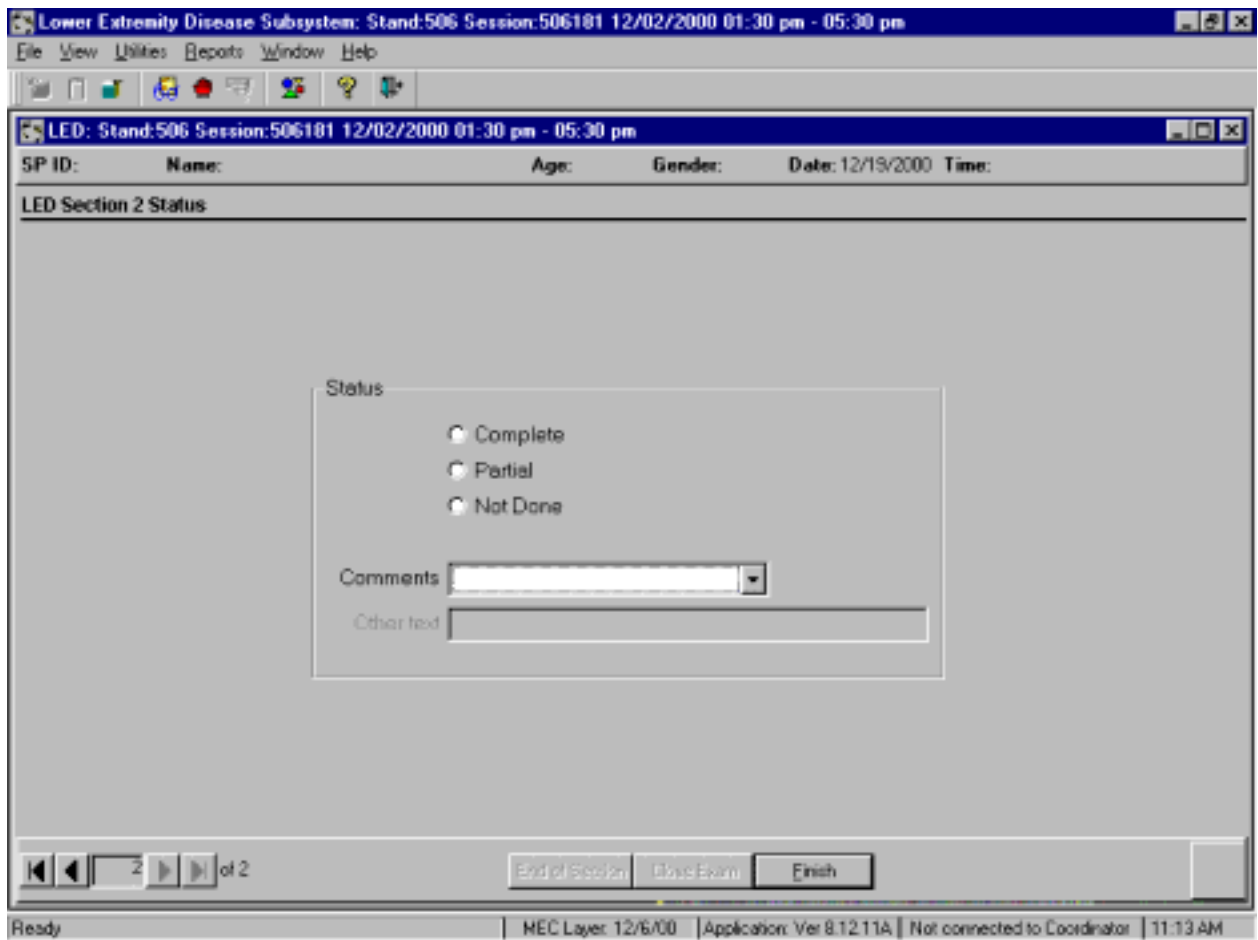
Screen 6: Section 1 Status Screen



Screen 7: ABPI Capture Screen (SPs age 40 - 59)



Screen 7: ABPI Capture Screen (SPs age 60+)



Screen 8: ABPI Section Status Screen

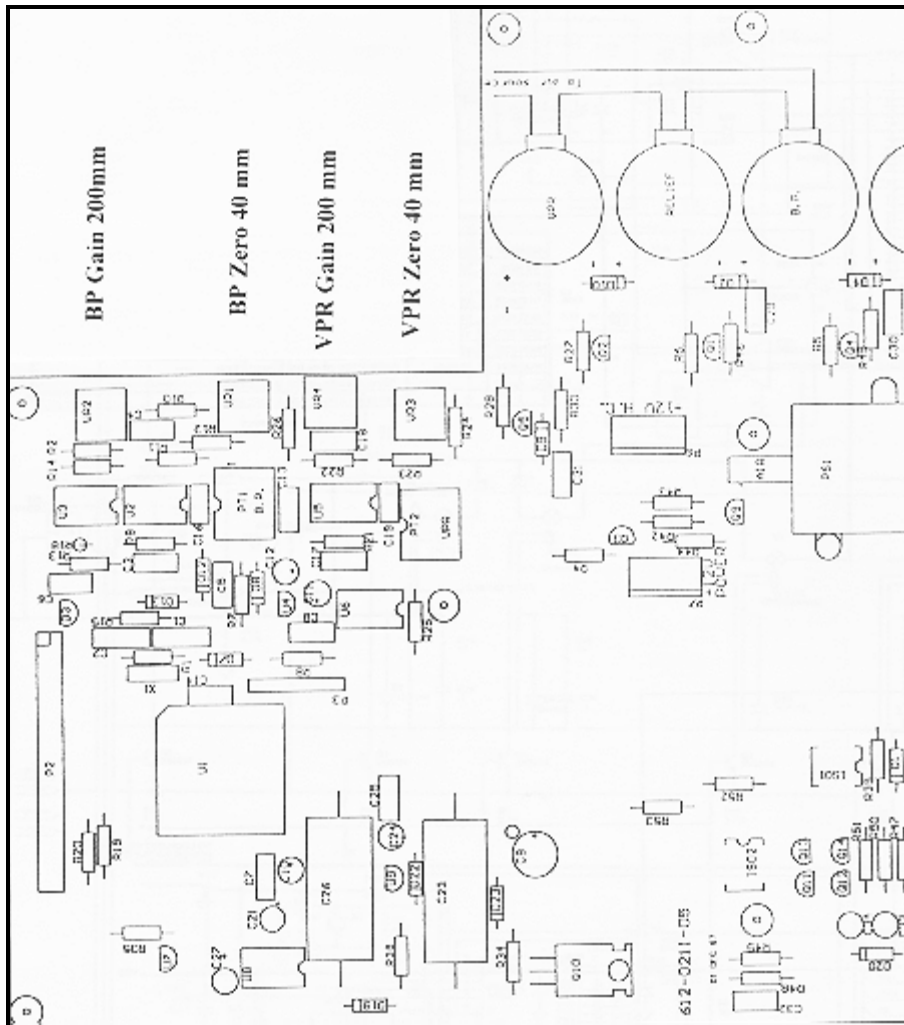
APPENDIX D. CALIBRATION ADJUSTMENT FOR THE PARKS MINI-LAB 3100

If the pressure reading on the Mini-Lab is more than ± 5 mm from the reading on the mercury manometer, the Mini-Lab must be adjusted.

Inform the MEC manager.

The MEC manager will contact the biomedical engineer who will make the following adjustments:

- Remove the top of the 3100 (Six screws on each side).
- Turn the unit on its left side.
- Remove the front two rubber feet and screws.
- Remove the four back panel screws. (NOTE: Mini-Lab may have star washers between back panel and chassis, or a ground strap. Be sure to replace these when reassembling the unit.)
- Mini-Lab should then be able to be split on its left side.
- Turn the unit so that the back panel is to your left and the front panel is away from and to the right, to expose the motherboard.
- There will be four variable resistors at the bottom right of the motherboard from left to right: VR3, VR4, VR1, VR2. (See figure on page 2.)
- Use a portable manometer and make the following adjustments:
 1. VR 1 and VR2 are for BP:
 - (a) VR1 is BP gain - calibrated at 200 mmHg (± 5).
 - (b) VR2 is BP zero - calibrated at 40 mmHg (\pm).
 2. VR 3 and VR4 are for VPR:
 - (a) VR3 is VPR zero - calibrated at 40 mmHg (± 5).
 - (b) VR4 is VPR gain - calibrated at 200 mmHg (\pm).



FigureD-1. Parks Mini-Lab 3100 inflator motherboard

- Refer to Diagram 2 in the Parks Medical Electronics Biomedical Engineering Manual, Model 3100, Vascular Mini-Lab with VIP.
- This manual is kept in the Room Supply box in the LED room in each MEC.
- The back panel of the Mini-Lab is on the right side of the diagram.
- VR1, VR2, VR3, and VR4 are labeled on the diagram.