

#### IV. Medical Examination Manuals

##### A. Audiometry Manual

###### 1. Introduction

###### a. Purpose

The procedures outlined in the present document are to be used in conjunction with the physical research to detect abnormalities in hearing. The hearing frequencies to be tested are 500 Hz, 1000 Hz, 2000 Hz, 3000 Hz, 4000 Hz, 6000 Hz, and 8000 Hz.

###### b. Normal Values for Audiograms

(1) An audiogram determines the threshold of hearing. It is measured in decibels of hearing loss. Normal hearing begins at 0 dba (decibels measured at the ear) and ranges to 40dba which is considered to be the extreme lower limit of normal. The following scale may be used for the clinical interpretation of audiograms.

(a) NORMAL	0-20 dba
(b) MILD LOSS	25-30 dba
(c) MODERATE LOSS	30-50 dba
(d) SEVERE LOSS	50-90 dba
(e) PROFOUND LOSS (DEAF)	90 dba

(2) Frequencies of 500, 1000, and 2000 Hz are considered "low frequencies" or "conversational tones". 3000, 4000, 6000, and 8000 Hz are considered "high frequencies". In many cases, an individual may have mild to severe loss in the "high frequencies" and normal hearing in the "low frequencies". This may be considered normal.

###### 2. Equipment

- a. RA400 Microprocessor Audiometer
- b. Tracoustic Medical Examination Room
- c. Paper (Tracor P/N 76499-0002)

(1) The RA400 Microprocessor Audiometer uses the power of a very small computer to manage the audiometric test administration.

- (2) For automatic testing of pure tone air conduction, the RA400 presents either a continuous one second tone or a one second burst consisting of three tone pulses. Tone (stimulus) presentations are random in order to lessen fraudulent responses. Each tone presentation opens a valid response period of 1.5 seconds during which the subject must press and release the handswitch for a good response.
- (3) The automatic program begins with a trial test at 1000 Hz for the first ear selected. The starting intensity is 30 dB Hearing Level (HL).
- (4) A negative response or no response at the initial 30 dB presentation will result in the audiometer increasing the HL by 20 dB to 50 dB. After this the intensity will increase by 10 dB until a positive response or 90 dB is reached. After the first positive or good response, the intensity is decreased by 10 dB for valid responses and raised 5 dB for invalid until a threshold is established. If, at the initial 30 dB presentation, a positive response is obtained, the audiometer goes into the -10 +5 dB pattern immediately. This attenuator control pattern serves to minimize test time.
- (5) All subject responses are stored along with all presentations of stimulus. Three positive responses at the same HL constitute hearing threshold for that frequency/ear. The test sequence then continues with 500, 1000, 2000, 3000, 4000, 6000, and 8000 for the first ear, then uses the same sequence for the opposite ear.
- (6) An explanation of how information is stored in the RA400 may help the operator to understand the audiometer operation. At the start of each test, initiated by pressing [NEW TEST] all previous information is deleted and an information table is set up in the computer. This table is similar to the audiogram form used for recording results when doing tests manually. Initially, the form or table would be blank. The operator would fill in subject information on the form. The operator does the same when entering information during the NEW TEST MODE. When the [RUN TEST] key is depressed, the RA400 starts at the top of the table and presents the first frequency, 1 kHz Test, validity test. When the hearing threshold is established, the HTL is entered into the table. Now to appreciate the power and programming of the RA400, consider that the operator can pause the automatic test, go to manual mode of operation, manually test any frequency and ear and the resulting HTL are then added to the computer table. If and when the audiometer is returned to automatic mode and [RUN

TEST] is pressed, the audiometer again starts at the top of the table and if the first frequency has been tested successfully, the audiometer goes to the next and so on. The operator has the control to administer tests as required by the subject. The operator can, at his or her discretion, retest any frequency manually, even frequencies that have been deleted from the automatic sequence or previously tested.

d. Maintenance of Equipment

- (1) The Tracor RA400 audiometer requires calibration once a year. This will be done by a qualified calibration technician from the company that supplies the equipment. Please refer to the Equipment Manual for more details.
- (2) A calibration check will be performed weekly on Monday before actual testing begins.

e. Procedure for Calibration Check

- (1) A baseline audiogram will be done on 2 individuals and the results documented.
- (2) Monday morning before actual testing, one of these individuals will be retested. The results of this testing must be within 5 dba of the baseline test data. The test subject must not have been exposed to loud noise within 15 hours, to avoid erroneous results. If the new audiogram result shows a threshold shift of more than 5 dba the audiometer will be checked by qualified servicing personnel.
- (3) A brief listening check will be performed daily by placing the audiometer in the accelerated listening mode. All frequencies are used and a tone presented to each ear to insure that the machine is functioning properly.
- (4) Poor print quality can be caused by lint built up on the print head of the electrostatic printer. The print head can be cleaned by rotating a pipe cleaner beside the print head.
- (5) Those users who fall under the guidelines of the Occupational Safety and Health Administration are required to have their audiometers checked every year and an exhaustive calibration every two years. The design of the RA400 is such that an exhaustive calibration does not require appreciable additional effort and therefore Tracor recommends that all users have their audiometers fully checked every year.

f. Testing Problems

<u>PROBLEM</u>	<u>SOLUTION</u>
(1) No TALK OVER	Talkover option not installed. Talkover microphone jack not completely seated.
(2) Left and right tone on.	Earphone jack not completely seated.
(3) Pressing [RUN TEST] causes printing of audiogram.	All frequencies have been tested resulting in an audiogram printout. Clear previous results with [NEW TEST] key.
(4) RESPONSE light stays on.	Sound room cabling problem. Plug earphone into audiometer to check.
(5) Audiometer does not function when turned on.	Check fuse. Check power circuit.
(6) Skips freq. during auto. test.	Frequency deleted.
(7) Will not respond to [SPECIAL] key push.	Did not exit previous SPECIAL routines. Press [SPECIAL] again.
(8) Will not respond to [NEW TEST] key push.	Did not exit previous SPECIAL routines. Press [SPECIAL] then [NEW TEST].

g. Paper Loading

- (1) The RA400 uses a metalized paper that provides an archive quality audiogram. Typically, one roll of paper lasts for 150 audiograms. A red strip will appear on the edge of the paper when the roll is nearing depletion.
- (2) To replace the paper (\*Use Tracor P/N 76499-0002) and do the following:
  - (a) Remove all the paper from the previous roll by turning the paper advance knob.

- (b) Place the new roll on the paper spindle. Place the loaded spindle in the slots in the paper spindle bracket. The loose end of the paper should come off the bottom of the roll and should feed up toward the front.
- (c) Feed the end of the paper as shown while turning the paper advance knob toward the rear of the printer until the paper comes out.

### 3. Procedure

This section is divided in several parts. The first part covers the most essential information for administering an automatic audiometric test. Subsequent parts give operation details on the many unique features of the RA400.

#### a. Initial Setup

The RA400 requires power connection to 120 volts AC 10%, 60 Hz (240 volts AC 10%, 50 Hz optional). The power receptacle should be marked "Hospital Grade" or "hospital Only" to comply with safety regulations. The handswitch, earphones and optional talk over microphone plugs should be inserted and seated firmly into the indicated jacks on the rear panel of the audiometer. Be sure that the serial number on the earphones matches the serial number of the audiometer. If an external computer or terminal is to be used, the connection is made to the RS232C connector on the rear panel. RS232C is an option. The optional microphone mounting adapter and stand can be attached to the bottom of the chassis at the left rear or right middle edge.

#### b. Essential Operating Information

The front panel is divided into pushbuttons or keys and displays. The displays indicate the operational status of the audiometer while the keys provide a means to control the audiometric test and to enter information.

##### (1) Displays

The display is divided into four sections labeled: FUNCTION, STATUS, FREQUENCY-Hz, and HEARING LEVEL.

- (a) The FUNCTION displays are back-lighted and are only visible when indicating a function. All the possible indicated functions are illustrated below:

- i. Auto
- ii. Tone
- iii. Left
- iv. Special
- v. Manual
- vi. Response
- vii. Right
- viii. Calibrate

- (b) The STATUS section indicates which of the frequencies have been tested by lighting a small bar to the left and right of the numbered frequency.
- (c) The FREQUENCY-Hz display section is used for a variety of displays, but mainly used to display the current audiometer frequency under test.
- (d) The HEARING LEVEL display section is also used for a variety of displays, but primarily for showing the current hearing level presented by the audiometer.

Two additional back-lighted legends are located below the FREQUENCY and HEARING LEVEL displays. These are TEST IN PROGRESS and TEST COMPLETE.

(2) Keyboard

The touch-sensitive keyboard panel is a unique product of technology that allows the placement of control switches behind a flat, durable overlay.

The essential keys for a basic automatic test are NEW TEST, RUN TEST, PAUSE, and the numeric keyboard.

<u>FRONT PANEL KEYS</u>	<u>EXPLANATION</u>
(a) [NEW TEST]	Starts or initializes each new subject test. Requests information such as I.D. numbers, shift number, etc.
(b) [RUN TEST]	Starts automatic test. Also resumes test if paused or halted for errors.
(c) [PAUSE]	Momentarily stops the automatic administration of the test. Can be restarted by [RUN TEST].

- (d) [CLR] [SPECIAL]            The numeric keypad located in the center of the keyboard is used for entry of identification numbers and test information.
- [1]    [2]    [3]
- [4]    [5]    [6]
- [7]    [8]    [9]
- (e) [NO]            [YES]            Used to answer questions when entering new participant data.

(f) Error Key

The [ERROR] key allows the operator a quick and easy way to review all previous errors. To review the errors press [PAUSE] if the test is IN PROGRESS and then [ERROR]. The previous error type and frequency will be displayed each time the key is pushed. When all errors have been displayed the routine will start over. If no errors are indicated, then "No Err" will be displayed. Push [RUN TEST] to resume testing.

The results of the test in progress can be reviewed at any time during the testing procedure. Simply press [PAUSE] noting that the TEST IN PROGRESS indicator goes off. The results are obtained by pressing the desired frequency and ear. The HEARING LEVEL display will display the HTL, if any, or a code indicating "not tested", "deleted" or "error". To resume the test, press [RUN TEST].

(g) Time Key

The [TIME] key displays the time of day in a 24 hour format. Time needs only to be entered at TURN-ON and will remain correct until the audiometer is again turned off. Remember, if the displayed time is greater than thirteen, subtract 12 and the time is in the afternoon, p.m.

If the audiometer is left on overnight, the date will be automatically advanced.

(h) Yes/No Key

The [YES], [NO] keys provide answers to questions. The response is displayed in the display.

(i) Talk Over Key

The optional talk-over function is controlled by the [TALK OVER] key. Pressing [TALK OVER] pauses the test, if in progress, and connects the TALK-OVER AMPLIFIER and mic to both of the subjects' earphones, and will also pause the printer if a print is in progress.

When the [TALK OVER] key is released, one of two conditions exist.

- (i) If a test was in progress when the key was pressed, the test will resume at the same frequency and ear, at an HL level of 30 dB, when the key is released.
- (ii) If a test was not in progress, the test is not resumed.

(3) Auditory Indicators

The RA400 has two auditory indicators. A faint click will confirm a key push, while an error will be signaled with a short tone or beep.

(4) Printer

- (a) The integral printer in the RA400 instructs the operator in information entry and generally guides the user as well as prints the audiogram.
- (b) The RA400 intentionally does not advance the printed instructions above the clear paper tear bar to conserve paper. The paper can be advanced by using the advance wheel to the left of the printer mechanism.

c. Basic Operation

After a quick overview of the displays and indicators, it is time to get started. The power switch is located on the left rear of the audiometer and should be moved up to turn on.

(1) Audiometer Turn-On

- (a) At TURN-ON several things start to happen. First, a loud tone or whistle is momentarily heard, then the printer starts printing, and in the display "Good 400" is displayed. A summary follows:

<u>FREQUENCY-HZ</u>	<u>HEARING LEVEL</u>	<u>PRINTER</u>
Good	400	Tracor Instruments, Austin, TX
		Computer OK. Please initialize audiometer by pressing [SPECIAL] [ENTER]

(b) If a computer error is discovered during the TURN-ON computer check, the following type of message will be displayed and printed:

<u>FREQUENCY-Hz</u>	<u>HEARING LEVEL</u>	<u>PRINTER</u>
Err	E8	Tracor Instruments, Austin, TX 43 01 ROM ERROR *****:*****
		DO NOT OPERATE  *****:*****
		CONTACT YOUR TRACOR REPRESENTATIVE FOR CORRECTIVE ACTION

(c) The value displayed in HEARING LEVEL shows the type of error, a hardware error in this case, and the printer will print out the corrective action.

(2) Initialize the Audiometer

(a) Following TURN-ON, the audiometer must be initialized. The following detailed example illustrates the information entry procedure. The example is divided between the display, both FREQUENCY and HEARING LEVEL, the printer and the keyboard. A number shown in the keyboard column indicates a key push. On the printer [] indicates a keyboard key. The [SPECIAL] key is an alternate action key. When pushed, it places the audiometer in the SPECIAL function and a second push terminates the SPECIAL FUNCTION.

<u>KEYBOARD</u>	<u>DISPLAY</u>	<u>PRINTER</u>
[SPECIAL]	SPC??	

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[0]          SPC 00
[ENTER]     SPC 00          ENTER DATE MMDDYY
                               (Example: Feb. 18, 1985)

[0]          0000 000
[2]          0000 002
[1]          0000 021
[8]          0000 218
[8]          0002 188
[2]          0021 882      DATE 02 18 85
                               ENTER EXAMINER ID#
                               9 DIGITS MAX (Example:
                               #1641)

[1]          0000 001
[6]          0000 016
[4]          0000 164
[1]          0001 641
[ENTER]     0001 641      EXAMINER ID#
                               000001641

                               MODE      PRESS
                               PULSED   [0]
                               CONTINUOUS [1]

[1]          0000 001
[ENTER]     0000 001      MODE CONTINUOUS

                               PRESS [NEW TEST] TO ENTER
                               PATIENT IDENTIFICATION

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(b) Once the RA400 initialization is complete, the information need not be re-entered until the next time the audiometer is turned on. Information entered during START-UP can be changed by going through the SPECIAL 00 again or using other special routines that change only one information item. In either case, the

information previously entered will be displayed and if the [ENTER] key is pushed, the same information will be retained.

(3) Clear Key

One final key that is used in conjunction with information entry is the [CLR] key. During information entry if the [CLR] key is pressed, the last number entered is deleted and the display shifts to the right by one digit.

(4) Test New Subject

The [NEW TEST] key prompts the question ENTER NEW PATIENT INFORMATION? YES/NO. If [NO] key is pressed, "NO" will print out and the audiometer returns to its last activity. If [YES] key is pressed the audiometer clears or erases all previous subject information and by use of instructions, guides the operator through the entry of new information for the present subject. Again, step by step examples will be given:

<u>KEYBOARD</u>	<u>DISPLAY</u>	<u>PRINTER</u>
[NEW TEST]	0000 000	ENTER NEW PATIENT INFORMATION? yes/n
[INITIALIZE] [YES]		ENTER PATIENT SS#/ID# (EXAMPLE: 457-70-1526)
[4]	0000 004	
[5]	0000 045	
[7]	0000 457	
[7]	0004 577	
[0]	0045 770	
[1]	0457 701	
[5]	4577 015	
[2]	5770 152	
[6]	7701 526	
[ENTER]	0000 000	SS#/ID# 457701526

ENTER PATIENT'S NOISE  
EXP? (Example: 14 hrs)  
Note: Six (6) digits  
max. The user may wish  
to choose a format that  
reflects hours since last  
exposure, dosimeter  
percentage, noise level  
at work station or work  
noise profile number.

[1] 0000 001

[4] 0000 014

[ENTER] 0000 000

NOISE EXP 000014

ENTER PATIENT TEST TYPE:  
(Example: 2) NOTE: One  
(1) digit max. The user  
may wish to choose a  
format that reflects the  
type of test:

TEST TYPE	CODE NUMBER
Baseline	1
Annual	2
Retest	3

[2] 0000 002

[ENTER] 0000 000

TEST TYPE 2

TYPE PROTECTOR?  
(Example: 1) NOTE: One  
(1) digit. The user may  
wish to choose a format  
that reflects the type  
hearing protection. As  
an example:

TYPE PROTECTION NUMBER	CODE NUMBER
None	0
Ear Plugs	1
Ear Muffs	2

[1] 0000 001

[ENTER] 0000 000

TYPE PROTECTOR 1  
BIRTH DATE MMDDYY  
(Example: 043044)

SEX F(0) M(1) (Example:  
Male)

[1]	0000 001	NOTE: Necessary for STS calculation
[ENTER]	0000 000	SEX MALE

#### 4. Participant Preparation

- a. The participant should be informed that his hearing will be tested from both ears. He should be instructed to listen for sounds and he should press the button when he hears a sound and release.
- b. The participant should then be seated in the Tracoustics Medical Exam Room and the headphones placed on his head with the red earphone on the right ear and the blue earphone on the left ear. The earphones should be adjusted so that they are in proper position over the external ear canal and so that they fit snugly. The door to the Tracoustics Medical Exam Room should be closed completely and any noise around the exam room area should be eliminated. The Run Test button on the Tracor unit should now be pressed.

#### 5. Information Displayed During Test

- a. The RA400 display provides the operator with information about how the audiometric test is proceeding. The FUNCTION displays indicate the test is in the AUTOMATIC mode of operation. The TONE and RESPONSE indicators light when the tone or stimulus is presented and the RESPONSE light indicates when the subject responds or presses the hand switch. The LEFT or RIGHT lights indicate which ear is being tested.
- b. The STATUS display indicates the frequencies that have been tested. With the successful completion of a test at each frequency, a small indicator will light to the left or right of the frequency legend. If the test could not be successfully completed, the indicator will blink. Also, if, at TURN ON, the frequency were deleted, the indicator will not light.
- c. During the test, FREQUENCY and HEARING LEVEL displays will change as the subject responds to the tones. The FREQUENCY display shows the current frequency being tested, the HEARING LEVEL indicates which level will be presented the next time the tone is "on", and the LEFT/RIGHT FUNCTION shows which ear.
- d. The TEST IN PROGRESS indicator, located under the frequency display, is illuminated during the automatic administration of the test. The indicator is turned on with the [RUN TEST] key,

turns off when the test is paused at the end of the test. The TEST COMPLETE indicator, located under the HEARING LEVEL display, indicates the end of the test.

#### 6. Test Completion

- a. The automatically administered test is completed when all the selected frequencies for both ears are successfully tested. The printer will print the audiogram containing the hearing threshold levels plus the subject and examiner information and, if selected, the baseline and standard threshold shift. The audiogram also contains the average of 2000, 3000 and 4000 Hz as well as the STS with presbycusis correction. (Marked STS/P on the threshold shifts printout). Additional copies of the audiogram can be printed by pressing the [PRINT] key. The audiometric test is complete and the next subject can be tested.
- b. The deleted questions (TEST TYPE and TYPE PROTECTOR) will not be asked again for any New Subject until the unit is turned off and back on or is reactivated with SPECIAL 12.

#### 7. Data Management

The following procedures will be followed for the collection and reporting of audiometric data:

- a. At the beginning of the day, the day's scheduling report will be distributed to the staff. This report will list each participant who is to have an audiogram for the day. The report does not list the participants in the order to be examined; however, it does show the schedule numbers (1-23) that the participants have been assigned.
- b. The scheduled participant will arrive.
- c. The technician will check off the participant on the daily schedule. This will provide an ongoing record of participants who have or have not been examined.
- d. The technician will perform the audiogram as described in this protocol manual. The technician will enter data on the hardcopy form.
- e. All of the audiograms will be administered in this manner by the technician. After all participants for the day have had their audiograms, the daily schedule will be given to the Clinic Manager for review and filing.

- f. Medical Records personnel will pick up the audiometry reports as described in the Medical Records Manual. Both the confirmed and unconfirmed reports will be collected. These reports will be taken to Data Processing.
- g. Data Processing will log and enter the test results, according to the procedure described in the Data Management Manual.
- h. After the test results have been entered, Medical Records personnel will collect the printouts and file them in the participants' records.

#### 8. Supervision

The bulk of the testing will be performed by electrodiagnostic technicians. Immediate supervision will be by registered nurses and the Clinic Manager who will have been trained to operate the RA400 Microprocessor Audiometer.

#### 9. Quality Control

The Clinic Manager, with the supervision of the Special Assistant for Quality Control and Scientific Affairs, will be responsible for administrative coordination of the quality control program, e.g., identifying and scheduling retests. The retest will be done in the manner described in the Data Management Manual. One participant will be selected each day to undergo a repeat audiometry exam. Results of the repeat exam will be compared to those of the original exam by the Medical Director and by the Quality Assurance Specialist. Any problems or deficiencies will then be quickly corrected so as to maximize the standardization of the audiometry test.

#### 10. Backup Equipment

For initial problems, LMC, Inc. Electronics Shop will be notified. If they are unable to correct the problem, Tracor Instruments, Austin, TX, will be informed. A second Tracor RA400 will be stored in the clinical area to be used as a backup.

#### 11. Subject Problems

If, during the course of testing, a participant decides to terminate or refuses the hearing test, the Clinic Manager will be notified. The participant then will be reminded of the importance of completing the test, recognizing that the individual has the right to refuse. If the participant at that time still decides not to continue the test a refusal with the signatures of the participant and the Clinic Manager will be entered into his record.

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#### IV. Medical Examination Manuals

##### B. Dermatology Manual

###### 1. Introduction

- a. This examination is meant to encompass the cutaneous portion of the physical examination, and to represent an inventory of significant findings. As with other sections, it was designed for reproducibility and to minimize observer bias. The examiner is expected to adhere to these general guidelines and directions.
- b. Definitions of the included skin conditions are generally uniformly accepted in current American dermatology, and there is little major disagreement among standard textbooks. The primary reference for this manual is: Fitzpatrick TB, Eisen AZ, Wolff K, Freedberg IM, and Austen KF. Dermatology in general medicine. 2nd ed. New York: McGraw-Hill, 1979.

###### 2. Guide to the Dermatology Examination

- a. The examination will be conducted with the participant in a variety of positions, including standing, sitting, and recumbent, so that the entire cutaneous surface may be clearly visualized. Proper lighting is of high importance and, ideally, should consist of more than one artificial light source as well as natural lighting. A combination of light sources, such as fluorescent and incandescent, especially when combined with natural light, will minimize color bias. A magnifying lens should be available. Wood's light examination should be possible although it need not be routine. Skin biopsy, culture or microscopic KOH preparations will not be done.
- b. In some areas, a grading system will be utilized. The qualification of the examiners should minimize variability; yet judgment will be called for. Where a standard grading system is not generally agreed upon, guidelines will be furnished.
- c. A camera is available in the examination room. It should be used to document any significant lesions. Photography will be documented as indicated on the data forms. Two photographs should be made of each lesion. The film will be processed when the roll is complete and each print will be included in the hardcopy medical report.

3. The Dermatology Examination

- a. SKIN COLOR TYPE [ ] (Range 1-6) 1. Always Burn, Never Tan 2. Usually Burn, Tan Slightly 3. Sometimes Burn, Average Tan 4. Rarely Burn, Tan More Than Average 5. Heavily pigmented 6. Blacks

Although this is usually determined historically, determination can be made on a clinical basis.

- b. PIGMENTATION [ ] 1. Absent 2. Present (If present enter location code and photograph code: 1. Yes 2. No) Findings should be in reference to participant's normal skin color.

HYPERPIGMENTATION [ ] [\_\_ \_\_ \_\_ \_\_] [ ]  
Do not include normal tanning of exposed areas, but do include exaggerated or abnormal tanning. Include melasma and postinflammatory hyperpigmentation. Enter lentigenes under neoplastic. Enter tinea versicolor under infectious.

HYPOPIGMENTATION [ ] [\_\_ \_\_ \_\_ \_\_] [ ]  
Include postinflammatory. Enter tinea versicolor under infectious. Enter pityriasis alba under miscellaneous causes. If true scarring exists, enter under trauma/factitial.

BIRTHMARK [ ] [\_\_ \_\_ \_\_ \_\_] [ ]  
Include hemangiomas (if obviously congenital), cafe-au-lait spots, and giant nevi.

OTHER CONDITIONS (SPECIFY) [ ] [\_\_ \_\_ \_\_ \_\_] [ ]

- c. HAIR [ ] 1. Absent 2. Present (If present enter location code and photograph code: 1. Yes 2. No)

ALOPECIA, MALE PATTERN [ ] [\_\_ \_\_ \_\_ \_\_] [ ]  
Primarily temple and crown.

ALOPECIA, SCARRING [ ] [\_\_ \_\_ \_\_ \_\_] [ ]  
Enter traumatic hair loss under trauma/factitial.

ALOPECIA, NONSCARRING AND NOT MALE PATTERN [ ] [\_\_ \_\_ \_\_ \_\_]  
[ ]  
Include alopecia areata.

HIRSUTISM [ ] [\_\_ \_\_ \_\_ \_\_] [ ]  
Special attention should be paid to temples and facial hair in non-beard areas, suggesting porphyria cutanea tarda or similar process.

OTHER CONDITIONS (SPECIFY) [ ] [\_\_ \_\_ \_\_ \_\_] [ ]

d. INFECTIONS [ ] 1. Absent 2. Present (If present enter location code and photograph code: 1. Yes 2. No)

ACNE, GR I [ ] [\_\_ \_\_ \_\_ \_\_] [ ]

Comedones and few pustules.

ACNE, GR II [ ] [\_\_ \_\_ \_\_ \_\_] [ ]

Pustules and small papules.

ACNE, GR III [ ] [\_\_ \_\_ \_\_ \_\_] [ ]

Papules and small cysts.

ACNE, GR IV [ ] [\_\_ \_\_ \_\_ \_\_] [ ]

Cystic or acne conglobata.

ACNE, ATYPICAL [ ] [\_\_ \_\_ \_\_ \_\_] [ ]

Unusual features or location. Use in addition to grade classification. Include acne of forearms, ears, etc., suggesting chloracne.

COMEDONES, ONLY [ ] [\_\_ \_\_ \_\_ \_\_] [ ]

No inflammatory lesions associated.

FOLLICULITIS [ ] [\_\_ \_\_ \_\_ \_\_] [ ]

Distinguish from keratosis pilaris.

HIDRADENITIS SUPPURATIVA [ ] [\_\_ \_\_ \_\_ \_\_] [ ]

Noncomedonal cystic involvement of intertriginous areas.

TINEA OF NAILS [ ] [\_\_ \_\_ \_\_ \_\_] [ ]

Determined on a clinical basis (no KOH or culture required). Include involvement by dermatophytes or candida.

CANDIDA [ ] [\_\_ \_\_ \_\_ \_\_] [ ]

Determined on a clinical basis; no KOH or culture (as per protocol).

TINEA VERSICOLOR [ ] [\_\_ \_\_ \_\_ \_\_] [ ]

TINEA (OTHER) [ ] [\_\_ \_\_ \_\_ \_\_] [ ]

Determined on a clinical basis; no KOH or culture (as per protocol).

OTHER CONDITIONS (SPECIFY) [ ] [\_\_ \_\_ \_\_ \_\_] [ ]

e. NEOPLASTIC [ ] 1. Absent 2. Present (If present enter location code and photograph code: 1. Yes 2. No)

ACROCHORDON [ ] [\_\_ \_\_ \_\_ \_\_] [ ]  
"Skin tags".

CANCER OF SKIN [ ] [\_\_ \_\_ \_\_ \_\_] [ ]  
Will not distinguish possible basal from squamous cell cancer.  
Exclude actinic keratoses. No biopsy will be done.

DERMATOFIBROMAS [ ] [\_\_ \_\_ \_\_ \_\_] [ ]  
Nodular subepidermal fibrosis. Exclude skin tags.

EPIDERMAL INCLUSION CYST [ ] [\_\_ \_\_ \_\_ \_\_] [ ]  
Include pilar cysts and pilomatrixomas.

KERATOSIS, ACTINIC [ ] [\_\_ \_\_ \_\_ \_\_] [ ]

KERATOSIS, SEBORRHEIC [ ] [\_\_ \_\_ \_\_ \_\_] [ ]

LENTIGINES [ ] [\_\_ \_\_ \_\_ \_\_] [ ]  
If striking or large.

LIPOMAS [ ] [\_\_ \_\_ \_\_ \_\_] [ ]

MILIA [ ] [\_\_ \_\_ \_\_ \_\_] [ ]  
Include facial as well as atypical or nonfacial areas.

NEVI, ATYPICAL [ ] [\_\_ \_\_ \_\_ \_\_] [ ]  
Include obvious congenital nevi under congenital.

SEBACEOUS HYPERPLASIA [ ] [\_\_ \_\_ \_\_ \_\_] [ ]

WARTS, NONGENITAL [ ] [\_\_ \_\_ \_\_ \_\_] [ ]

OTHER CONDITIONS (SPECIFY) [ ] [\_\_ \_\_ \_\_ \_\_] [ ]

f. VASCULAR [ ] 1. Absent 2. Present (If present, enter location  
code and photograph code: 1. Yes 2. No)

BRUISES [ ] [\_\_ \_\_ \_\_ \_\_] [ ]  
Major concern is for easy bruisability.

CAPILLARITIS [ ] [\_\_ \_\_ \_\_ \_\_] [ ]  
Mainly, but not confined to, legs. Include Schamberg's disease  
group, mild stasic changes, and hemosiderosis.

HEMANGIOMAS, NOT SPIDER [ ] [\_\_ \_\_ \_\_ \_\_] [ ]  
Include cherry angiomas.

PALMAR ERYTHEMA [ ] [\_\_ \_\_ \_\_ \_\_] [ ]

POIKILODERMA OF CIVATTE [ ] [\_\_ \_\_ \_\_ \_\_] [ ]  
Lateral surfaces and "V" of neck.

SPIDER ANGIOMAS [ ] [\_\_ \_\_ \_\_ \_\_] [ ]

TELANGIECTASIAS [ ] [\_\_ \_\_ \_\_ \_\_] [ ]  
Include small vascular mats.

VASCULITIS, OTHER [ ] [\_\_ \_\_ \_\_ \_\_] [ ]  
Exclude capillaritis.

VARICOSITIES [ ] [\_\_ \_\_ \_\_ \_\_] [ ]

OTHER CONDITIONS (SPECIFY) [ ] [\_\_ \_\_ \_\_ \_\_] [ ]

g. SEXUALLY TRANSMITTED DISEASE [ ]

1. Absent 2. Present (if present enter location code and  
photograph code: 1. Yes 2. No)

EXANTHEMS [ ] [\_\_ \_\_ \_\_ \_\_] [ ]  
Major concern is secondary syphilis. Distinguish from  
eczematous dermatitis.

HERPETIFORM LESIONS [ ] [\_\_ \_\_ \_\_ \_\_] [ ]  
Include herpes labialis and herpes progeneralis. Include scars  
under Scars, postinflammatory.

ULCERS [ ] [\_\_ \_\_ \_\_ \_\_] [ ]  
Anogenital, include aphthosis under inflammatory unless strongly  
suspicious.

CONDYLOMATA [ ] [\_\_ \_\_ \_\_ \_\_] [ ]  
Include condyloma acuminata and condyloma lata.

OTHER CONDITIONS (SPECIFY) [ ] [\_\_ \_\_ \_\_ \_\_] [ ]

h. TRAUMA/FACTITIAL [ ]

1. Absent 2. Present (If present, enter location code and  
photograph code: 1. Yes 2. No)

DRUG TRACKS [ ] [\_\_ \_\_ \_\_ \_\_] [ ]  
Suspicion and discretion advised.

SCARS, POSTINFLAMMATORY [ ] [\_\_ \_\_ \_\_ \_\_] [ ]  
Include post-zoster, porphyria cutanea tarda.

SCARS, SURGICAL [ ] [\_\_ \_\_ \_\_ \_\_] [ ]

SCARS, TRAUMATIC [ ] [\_\_ \_\_ \_\_ \_\_] [ ]  
Include burn scars and traumatic (e.g., "pavement") tattoos.

TATTOOS [ ] [\_\_ \_\_ \_\_ \_\_] [ ]

OTHER CONDITIONS (SPECIFY) [ ] [\_\_ \_\_ \_\_ \_\_] [ ]

i. INFLAMMATORY [ ]

1. Absent 2. Present (If present enter location code and photograph code: 1. Yes 2.No)

APHTHOSIS [ ] [\_\_ \_\_ \_\_ \_\_] [ ]

Distinguish from sexually transmitted disease.

BULLAE [ ] [\_\_ \_\_ \_\_ \_\_] [ ]

VESICLES [ ] [\_\_ \_\_ \_\_ \_\_] [ ]

DERMATITIS, ECZEMATOUS [ ] [\_\_ \_\_ \_\_ \_\_] [ ]

Need not distinguish etiology.

DYSHIDROSIS [ ] [\_\_ \_\_ \_\_ \_\_] [ ]

LICHEN SIMPLEX CHRONICUS [ ] [\_\_ \_\_ \_\_ \_\_] [ ]

Localized chronic neurodermatitis. Include prurigo nodularis.

LICHEN PLANUS [ ] [\_\_ \_\_ \_\_ \_\_] [ ]

PSORIASIS [ ] [\_\_ \_\_ \_\_ \_\_] [ ]

Distinguish from seborrhea, especially if scalp is involved.

EXCORIATIONS [ ] [\_\_ \_\_ \_\_ \_\_] [ ]

Include erosions and crusting.

SEBORRHEIC DERMATITIS [ ] [\_\_ \_\_ \_\_ \_\_] [ ]

Include facial if not clearly rosacea.

ROSACEA [ ] [\_\_ \_\_ \_\_ \_\_] [ ]

Distinguish from acne.

ANGULAR STOMATITIS [ ] [\_\_ \_\_ \_\_ \_\_] [ ]

Perleche.

URTICARIA [ ] [\_\_ \_\_ \_\_ \_\_] [ ]

Include gyrate erythemas under "OTHER".

OTHER CONDITIONS (SPECIFY) [ ] [\_\_ \_\_ \_\_ \_\_] [ ]

j. MISC. CAUSE [ ] 1. Absent 2. Present (If present, enter location code and photograph code: 1. Yes 2. No)

ASTEATOSIS (XEROSIS) [ ] [\_\_ \_\_ \_\_ \_\_] [ ]

Include what may be termed ichthyosis vulgaris.



#### 4. Data Management

##### a. General

- (1) A data collection form has been designed that will provide for input of all relevant data. Through the use of the structured form, complete examinations are assured. This form will be utilized by the physician during the examination for recording abnormalities. Built into the data collection form are skip patterns which will help to ensure that only results relevant to a specific participant will be entered. At the conclusion of the recording process, the form will be reviewed by the physician for errors and subsequently will become part of the hard copy medical record.

##### b. Data Collection

- (1) The Dermatology exam will be given and all responses, both free text and coded, will be entered onto the data collection form by the physician. This procedure will provide the most accurate and immediate capture of the needed information.
- (2) The following procedures will be followed for the collection and reporting of medical data:
  - (a) Step 1: At the beginning of the day, the day's scheduling report will be distributed to the staff. This report will list each participant that is to have a Dermatology exam for the day. The report does not list the participants in the order to be examined, however, it does show the schedule numbers (1-23) that the participants have been assigned.
  - (b) Step 2: The scheduled participant will arrive.
  - (c) Step 3: The physician will check off the participant on the daily schedule. This will provide an ongoing record of participants that have or have not been examined.
  - (d) Step 4: The physician will perform the dermatology examination. During the exam, he/she will note abnormalities on the data collection form. Without exception, the results have all been coded. Coding appears on the data form to facilitate a quick entry process.

- (e) Step 5: After the examination is complete, the physician will enter the medical record number assigned to the participant, the date, the physician's ID #, the exam start time and the exam status.
- (f) Step 6: After the physician has completed entry of the results, he/she will enter the exam completion time.
- (g) Step 7: The physician will review the printed results. The printed narrative will contain the translation for the codes entered, thereby providing easier identification of errors. If errors are found, the physician will go to the incorrect answer and correct it.
- (h) Step 8: The physician may have comments or impressions regarding the examination that he/she wishes to highlight. In these cases, the physician will handscribe on the bottom of the narrative any such remarks.
- (i) Step 9: Once the physician is satisfied with the accuracy of the exam, he/she will verify the printed narrative by signing it.
- (j) Step 10: The physician will take the printed narrative to the nursing station and place it in the appropriate exam slot.
- (k) Step 10: The physician is now ready for the next participant and will continue with steps 2-9 until all participants for the day have been examined.
- (l) Step 11: After all participants have been examined, the daily schedule should be taken to the Clinic Manager and filed.

#### 5. Quality Control

- a. Requirement for examiners who are board-certified or board-eligible in dermatology.
- b. Certification of the ability of the examiners to perform the dermatology exam in the standard manner.
- c. Performance of blind, repeat examinations (one per day) on participants randomly selected according to the procedure described in the Data Management Manual.
- d. Assessment of inter-examiner variability in findings.

6. Backup

Backup examiners will be provided from the group of board-certified dermatologists participating in the study.

7. Supervision

All examinations will be conducted under the supervision of the Medical Director.

8. Subject Problems

If, during the course of testing, a participant decides to terminate or refuse the dermatology examination, the Clinic Manager will be notified. The participant will then be reminded of the importance of completing the test, recognizing that the individual has the right to refuse. If the participant, at that time, still decides not to continue the test, a refusal will be entered into his record.

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#### IV. Medical Examination Manuals

##### C. Electrocardiogram

###### 1. Introduction

A standard 12-lead electrocardiogram (ECG) will be obtained from all examinees using the Marquette MAC II automated ECG machine. If, during the performance of the ECG, the machine detects the presence of an arrhythmia, a one-minute rhythm strip is automatically recorded. The machine transfers the data via a modem connection to the Lovelace Section of Cardiology where it is interpreted by a board-certified cardiologist. The hardcopy of tracings will be mounted in the usual manner and then forwarded along with the cardiologist's review and interpretation to the hardcopy medical record for data entry and review by the Project Diagnostician. Accordingly, the ECG will be recorded early during the first morning, proximate to the initial first morning laboratory specimen drawing. Instructions related to the fasting and caffeine abstinence requirements are included in the examinee's information packet and will be orally explained to each examinee by the participant advocate (host) the evening before the examination day.

###### 2. Equipment

- a. Marquette Microcomputer Augmented Cardiograph (MAC) II automated ECG machine.

- (1) Maintenance of the ECG machine will be performed as necessary by the electronics shop at LMC using the service manual for MAC II, PP 7-1 through 7-59 inclusive and/or the Operator's Manual for MAC II pp. 6-1 through 6-2. These manuals may be found with the Marquette carts. Maintenance and calibration information is also contained in the Equipment Manual.

- b. Electrode Paste

###### 3. Preparing Equipment

- a. Insert power cord plug into appropriate wall receptacle. Ensure power source is same voltage and frequency as specified on nameplate at rear of unit. The AC outlet must be for a grounded plug.
- b. Connect participant cable to connector on front of unit. Ensure internal switches are set for desired characteristics.

- c. Depress ON part of power switch. After self test, selected filter, writer speed, gain, and rhythm lead group should be displayed on an alphanumeric display.

#### 4. Preparing Participant

- a. Obtain resting participant cable, suction electrodes, rubber straps, limb electrodes, and back electrode.
- b. Before electrodes can be placed, have participant remove upper garments to facilitate placement of electrodes.
- c. Have participant lie flat on his back preferably on a comfortable bed, cot, or reclining chair with arms relaxed at sides.
- d. Place lead wires with distribution block at either left or right side of participant or on participant's stomach. If wires are tangled, separate them before proceeding. When separating the wires, do not attempt to jerk or pull wires as this could result in damage to the wire at the distribution block.
- e. If participant's skin is extremely oily, scaly, or sweaty, clean with soap and water or alcohol.
- f. Before electrode placement, apply small amount of electrode paste to skin surface at electrode site to ensure good contact. Using rim of suction cup or tongue depressor, rub electrode paste into skin approximately five times or until skin becomes reddened.
- g. Apply four limb lead electrodes (RA, LA, RL, and LL) to extremities with straps provided. A variation of limb lead placement is to place the suction electrodes on the upper arms (outer shoulders) and upper thighs; particularly if the participant is very large. This alternate method generally minimizes muscle tremor.

##### (1) Limb Lead Placement

Apply four limb lead electrodes to participant as follows:

- (a) RA--right arm at wrist,
- (b) LA--left arm at wrist,
- (c) RL--right leg, above ankle, and
- (d) LL--left leg, above ankle

NOTE: Be careful not to use an excessive amount of electrode paste, especially on the chest electrode sites, and do not allow the electrode paste from one position to come in contact with the electrode paste

of another position. If this occurs, the tracings from those leads may appear distorted to the physician reading the ECG.

(2) Precordial Lead Placement

Determine the best routing and placement of precordial suction electrodes. Locations for the chest electrodes are:

- (a) V1--fourth intercostal space at right border of sternum,
- (b) V2--fourth intercostal space at left border of sternum,
- (c) V3--midway between positions V2 and V4,
- (d) V4--at the midclavicular line and the interspace in which the apex is located (the fifth intercostal space is used if the apex is not palpable),
- (e) V5--at the anterior axillary line on a horizontal level with V4, and
- (f) V6--at the midaxillary line on the same horizontal level as V4 and V5.

NOTE: To eliminate interference with adjoining electrode, the chest electrode sites should be rubbed up and down rather than from side to side. After all suction electrodes are on participant, connect banana plug at end of each lead wire to appropriate electrode.

NOTE: The banana plugs on the participant cable. Lead wires are color coded in compliance with either the AHA or IEC color coding specification. All limb leads must be connected. Any unused V lead electrodes must go into the ground jacks in the distribution block of the participant cable.

5. Resting ECG (Commercial Equipment)

- a. Ensure unit and participant have been prepared as described previously.
- b. To change filter, writer speed, gain, and/or rhythm lead group, depress CHANGE key and perform applicable substep.
  - (1) For rhythm lead group, depress 6 for V1 + V2 + V3, V4 + V5 + V6, V1 + I1 + V5, I + I1 + I11, or aVR + aVL + aVF.
  - (2) For filter change, depress 7 for either 40 Hz or 100 Hz.

(3) For chart paper speed, depress 8 for 1, 5, 25, 50, or 100 mm/s.

(4) For signal gain, depress 9 for 2.5, 5, 10, or 20 mm/mV.

c. Depress ENTER key. Respond to questions and/or enter data listed in following substeps.

DIFFERENT PATIENT? X (1 digit) 1=yes 0=no

NOTE: The following two substeps are applicable only for units with the alphanumeric keyboard.

LAST NAME X...X (20 char) Alpha only

FIRST NAME X...X (20 char) Alpha only

NOTE: The correct number of digits are required for the ID number. If an insufficient number of digits is entered, the prompt "EXACT # DIGITS" appears. By entering the correct number based on internal switch settings, the unit will accept the entry.

PATIENT ID #	X...X (5 to 12 digits)	Numeric only
AGE	XX (2 digits)	Numeric only
HEIGHT/INCHES	XXX (3 digits)	Numeric only
WEIGHT	XXX (3 digits)	In pounds
SEX	X (1 digit)	0=male 1=female
RACE (0-4)	X (1 digit)	0=caucasian 1=black 2=oriental 3=hispanic 4=unspecified
MEDICATION (0-9)	X (1 digit)	0=none 1=digitalis 2=Quinidine 3=beta blocker 4=Procainamide 5=lidocaine 6=Disopyramide 7=diphenylhydantoin 8=diuretic 9=psychotropic
LOCATION	XX (2 digits)	00 - 99

NOTE: The following three prompts appear only if internal switches are set for the prompt displays.

OPTION	XX (2 digits)	00 - 99
SYSTOLIC BP	XXX (3 digits)	050 - 299
DIASTOLIC BP	XXX (3 digits)	000 - 199

Display returns to filter, speed, gain, and rhythm group selection.

d. Depress RECORD ECG switch. Following actions should occur.

NOTE: ECG data are acquired immediately upon participant connection. The word "ACCEPTED" may appear almost immediately after the RECORD ECG switch is depressed. The time in seconds will appear in the lower right corner of the display from the point the switch is depressed until 10 seconds of valid ECG data are obtained. If the unit detects a fault condition the electrode(s) at fault is displayed. After correcting the fault, the fault condition is no longer displayed and the time in seconds is displayed until 10 seconds of valid ECG data are acquired. The word "ACCEPTED" will then appear and the ECG will be recorded.

- (1) For nonerror condition, word "ACCEPTED" should appear momentarily on display after 10 seconds of ECG data are acquired. The words "ANALYZING ECG" then appear. Approximately 8 seconds after acquiring data, chart paper should run up (if selected) at preselected speed recording straight lines. ECG recording should begin at perforation at preselected chart paper speed. ECGs selected in unit setup are recording in sequence. Extra copies are recorded following first complete record. If runout is selected, chart paper should run out to perforation.
- (2) For error condition during acquisition, the lead(s) at fault will be displayed. Two alternatives exist.
- (3) Correct fault, either by reapplying electrode(s) or holding electrode(s) on participant. Once fault(s) is corrected, unit will automatically begin recording ECG after 10 seconds of valid ECG data is acquired. Word "ACCEPTED" will appear and recording of ECG should begin approximately 8 seconds later.
- (4) Depress RECORD ECG switch to record ECG without correcting fault.

e. Tear off applicable ECG form(s).

f. Depress STOP switch to reset display and clear internal memory. Display returns to filter, writer speed, gain, and rhythm lead group selection.

g. If applicable, proceed to shutdown procedure.

Following recording, compression of ECG occurs for 5 to 8 seconds.

After compression, unit records ECG on tape. Following message should be displayed.

ID number Name  
WRITING TO DATA-PAK

Upon completion of recording on tape, following message is displayed.

ID number Name  
RECORD X

For error condition during recording, "DATA-PAK FAULT?", "DATA-PAK FULL", "NOT DATA-PAK FORMAT", or "MAC-1 DATA-PAK" message may be displayed.

For "DATA-PAK FAULT?" error, ensure tape cartridge is installed.

For "DATA-PAK FULL" error, install other tape cartridge.

For "NOT DATA-PAK FORMAT" error, obtain properly formatted tape cartridge and install.

For "MAC-1 DATA PAK" error, select applicable entry on menu or obtain MAC II tape and install.  
If desired, note record number.

h. Depress STOP switch. Display returns to filter, speed, gain, and rhythm group selection.

## 6. Data Management

- a. The ECG will be administered by a technician using the Marquette SmartCarts. The Marquette SmartCart will transmit the test data, via telephone wires, to the Marquette Muse Automated ECG system in the Cardiology Department. A printout is generated which includes the waveform, certain numeric results and an unconfirmed computerized interpretation. This output will be overread by a cardiologist and any changes will be entered into the Marquette system. After this interpretation, another printout will be generated. Then both the unconfirmed and confirmed results will be forwarded to Data Processing. Data Processing will input the results according

to the method described in the Data Management Manual. Once completed, the printed results will be forwarded to Medical Records for filing in the participant's chart.

- b. The following procedures will be followed for the collection and reporting of ECG data:
- (1) At the beginning of the day, the day's scheduling report will be distributed to the staff. This report will list each participant that is to have an ECG for the day. The report does not list the participants in the order to be examined; however, it does show the schedule numbers (1-23) that the participants have been assigned.
  - (2) The scheduled participant will arrive.
  - (3) The technician will check off the participant on the daily schedule. This will provide an ongoing record of participants that have or have not been examined.
  - (4) The technician will perform the ECG as described in the protocol manual.
  - (5) After the technician has completed the test, the ECG data will be transmitted to the Marquette system. If the Marquette system is down for any reason, the ECG data are stored in the data pack that is a part of the SmartCarts. After the Marquette system is back online, the data can be transmitted to it. This procedure is outlined in the operation procedures of the Marquette SmartCarts.
  - (6) All of the ECGs will be administered in this manner by the technician. After all participants for the day have had their ECGs, the daily schedule will be given to the Clinic Manager for review and filing.
  - (7) Once the data are received by the Marquette system, the technicians in the heart station (cardiology) will generate the unconfirmed reports. These reports will include the waveform, certain numerical values and the computerized interpretation. They will be labeled as unconfirmed reports.
  - (8) The heart station technicians will take the printed reports to the cardiologists.
  - (9) The cardiologists will overread the ECG reports, indicating on the reports any corrections that are warranted and using the coding system included in this manual.
  - (10) The heart station technicians will enter the corrections made by the cardiologist, if any, and generate a confirmed ECG report. This report will include the name of the

cardiologist that overread it, as well as the other information included on the unconfirmed report.

- (11) Medical Records personnel will pick up the ECG reports as described in the Medical Records manual. Both the confirmed and unconfirmed reports will be collected. These reports will be taken to Data Processing.
- (12) Data Processing will log and enter the test results, as described in the Data Management Manual.
- (13) After the test results have been entered, Medical Records personnel will collect the forms and file them in the participants' records.

#### 7. Supervision

Supervision of ECG technicians will be provided by the Lovelace Cardiology Department in conjunction with the Clinic Manager. Ongoing evaluation of technicians is according to the policies and requirements of the Cardiology Department. Technical problems with the electrocardiogram should first be addressed to the Clinic Manager, and then if necessary, should be addressed to the appropriate member of the Cardiology Department (i.e., ECG technician supervisor or cardiologist). Questions or problems regarding participants, schedules, supplies, etc. should be addressed to the Clinic Manager.

#### 8. Quality Control

Quality control of the ECG reading is provided by the overreading of the machine interpretation by a board certified cardiologist in all cases. If the cardiologist feels that there is a problem with the ECG tracing, the participant will be found, and the ECG will be repeated before the end of Medical Exam Day.

#### 9. Backup Equipment

- a. In the event the on-site ECG machine is unable to function or immediate interpretation is lost, the tape recording option of the ECG output will be utilized and hand-carried to the Cardiology Department. If needed, the above can be typed into the terminal.
- b. Procedure for handling equipment problems will be handled first by observing the "Troubleshooting Guide" in the MAC II Operator's Manual 7-1 through 7-2; then by observing "Illustrated Parts Breakdown" section VIII pp. 8-1 through 8-2 in the Service Manual for MAC II. A service contract is purchased for the Marquette Computer System. If necessary, backup carts are available from the Lovelace Medical Center Cardiology Department.

10. Backup Technician

Technician backup will be provided from the pool of ECG technicians in the Cardiology Department. All technicians will have had training as required to perform their duties in the Cardiology Department.

11. Subject Problems

If, during the course of testing, a participant decides to terminate or refuses the ECG, the Clinic Manager will be notified. The participant will then be reminded of the importance of completing the test, recognizing that the individual has the right to refuse. If the participant, at that time, still decides not to continue the test a refusal will be entered into his record.

## 12. Appendix I

## a. Coding

<u>ACRONYM</u>	<u>INTERPRETATION</u>	<u>CODE</u>
ARAT	ATRIAL RATE	0020
SBRAD	SINUS BRADYCARDIA	0021
NSR	NORMAL SINUS RHYTHM	0022
STACH	SINUS TACHYCARDIA	0023
MSBRAD	MARKED SINUS BRADYCARDIA	0024
JBRAD	UNUSUAL P AXIS AND SHORT PR, PROBABLE JUNCTIONAL BRADYCARDIA	0041
JR	UNUSUAL P AXIS AND SHORT PR, PROBABLE JUNCTIONAL RHYTHM	0042
JTACH	UNUSUAL P AXIS SHORT PR, PROBABLE JUNCTIONAL TACHYCARDIA	0043
EABRAD	UNUSUAL P AXIS, POSSIBLE ECTOPIC ATRIAL BRADYCARDIA	0061
EAR	UNUSUAL P AXIS, POSSIBLE ECTOPIC ATRIAL RHYTHM	0062
EATACH	UNUSUAL P AXIS, POSSIBLE ECTOPIC ATRIAL TACHYCARDIA	0063
FAV	WITH 1ST DEGREE A-V BLOCK	0101
SPR	WITH SHORT PR	0102
MBZI	WITH 2ND DEGREE A-V BLOCK (MOBITZ)	0103
MBZII	WITH 2ND DEGREE A-V BLOCK (MOBITZ II)	0104
SAV	WITH 2ND DEGREE A-V BLOCK	0105
CHB	WITH COMPLETE HEART BLOCK	0106
VAVB	WITH VARIABLE A-V BLOCK	0107
ADVIS	WITH A-V DISSOCIATION	0108
SABII	WITH 2ND DEGREE SA BLOCK (MOBITZ II)	0111
SABI	WITH 2ND DEGREE SA BLOCK (MOBITZ I)	0112
PAUSE	WITH SINUS PAUSE	0113
W2T1	WITH 2:1 A-V CONDUCTION	0141
W3T1	WITH 3:1 A-V CONDUCTION	0142
W4T1	WITH 4:1 A-V CONDUCTION	0143
W5T1	WITH 5:1 A-V CONDUCTION	0144
AFIB	ATRIAL FIBRILLATION	0161
FLUT	ATRIAL FLUTTER	0162
CRS	COARSE	0163
ATAC	ATRIAL TACHYCARDIA	0164
RVR	WITH RAPID VENTRICULAR RESPONSE	0171
SVR	WITH SLOW VENTRICULAR RESPONSE	0172
ABER2	WITH PREMATURE VENTRICULAR OR ABERRANTLY CONDUCTED COMPLEXES	0173
CJP	WITH A COMPETING JUNCTIONAL PACEMAKER	0174
IRREG	WITH UNDETERMINED RHYTHM IRREGULARITY	0175
ABER	WITH PREMATURE VENTRICULAR OR ABERRANTLY CONDUCTED COMPLEXES	0181
OCC	WITH OCCASIONAL	0211
FREQ	WITH FREQUENT	0212
PSVC	PREMATURE SUPRAVENTRICULAR COMPLEXES	0221
PAC	PREMATURE ATRIAL COMPLEXES	0222
PJC	PREMATURE JUNCTIONAL COMPLEXES	0223
PVC	PREMATURE VENTRICULAR COMPLEXES	0231
PYCF	PREMATURE VENTRICULAR AND FUSION COMPLEXES	0232

<u>ACRONYM</u>	<u>INTERPRETATION</u>	<u>CODE</u>
CSEC	AND CONSECUTIVE	0233
BIGEM	IN A PATTERN OF BIGEMINY	0234
PEC	PREMATURE ECTOPIC COMPLEXES	0241
JESC	WITH JUNCTIONAL ESCAPE COMPLEXES	0242
VESC	WITH VENTRICULAR ESCAPE COMPLEXES	0243
SAR	WITH SINUS ARRHYTHMIA	0251
MSAR	WITH MARKED SINUS ARRHYTHMIA	0252
PR-SBRAD	PROBABLE SINUS BRADYCARDIA, VERIFY A-V CONDUCTION	0265
SUP-TACH	SUPRAVENTRICULAR TACHYCARDIA	0266
JUNCT-R	JUNCTIONAL RHYTHM	0267
IDIO-R	IDIOVENTRICULAR RHYTHM WITH IV BLOCK	0268
VENT-RTH	VENTRICULAR RHYTHM	0269
J-TACH	JUNCTIONAL TACHYCARDIA	0270
SUP-TACH2	SUPRAVENTRICULAR TACHYCARDIA	0271
VTACH	VENTRICULAR TACHYCARDIA (VENTRICULAR OR SUPRAVENTRICULAR WITH ABERRATION)	0272
AFL	ATRIAL FLUTTER	0273
VENT-FUS	WITH VENTRICULAR FUSION	0274
JESC	WITH JUNCTIONAL ESCAPE	0275
ESCBT	WITH ESCAPE BEAT	0276
TVT	WITH TRANSIENT VENTRICULAR TACHYCARDIA	0277
WEKH	WITH MOBITZ I (WENCKENBACH) BLOCK	0278
PO-ATP	POSSIBLE WANDERING ATRIAL PACEMAKER	0279
MULT-AT	MULTIFOCAL ATRIAL TACHY/CARDIA0280	
COMP-HB	COMPLETE HEART BLOCK	0281
AV-COND	SUSPECT A-V CONDUCTION DEFECT	0282
AB-VENT	WITH INTERMITTENT ABERRANT VENTRICULAR CONDUCTION	0283
SA-BLK	WITH S-A BLOCK OR TRANSIENT A-V BLOCK	0284
SAB	WITH SINUS ARREST OR TRANSIENT A-V BLOCK	0285
LHR	LOW HEART RATE, VERIFY A-V CONDUCTION	0287
AFL-BL	ATRIAL FLUTTER WITH 2 TO 1 BLOCK	0288
PCK	ELECTRONIC VENTRICULAR PACEMAKER	0290
DPCK	DEMAND PACEMAKER; INTERPRETATION IS BASED ON INTRINSIC RHYTHM	0291
APCK	ELECTRONIC ATRIAL PACEMAKER	0292
AVPCK	AV SEQUENTIAL OR DUAL CHAMBER ELECTRONIC PACEMAKER	0293
UR	UNDETERMINED RHYTHM	0299
WPWA	VENTRICULAR PRE-EXCITATION, WPW PATTERN TYPE A	0300
WPWB	VENTRICULAR PRE-EXCITATION, WPW PATTERN TYPE B	0302
ALTWPW	WITH FUSION OR INTERMITTENT VENTRICULAR PRE-EXCITATION (WPW)	0303
CUR-UND	CURRENT UNDETERMINED RHYTHM PRECLUDES RHYTHM COMPARISON, NEEDS REVIEW	0320
PRV-UND	PREVIOUS ECG HAS UNDETERMINED RHYTHM NEEDS REVIEW	0321
VENT-RAT	VENT, RATE	0322
RHY	RHYTHM	0323
PRM-CON	THE PREMATURE CONTRACTIONS	0324
CONSEC	CONSECUTIVE	0325
WITH-DEM	WITH A DEMAND PACEMAKER	0326
BASIC	BASIC RHYTHM	0327

<u>ACRONYM</u>	<u>INTERPRETATION</u>	<u>CODE</u>
RAE	RIGHT ATRIAL ENLARGEMENT	0350
LAE	LEFT ATRIAL ENLARGEMENT	0360
BAE	BIATRIAL ENLARGEMENT	0369
LAD	LEFTWARD AXIS	0370
ALAD	ABNORMAL LEFT AXIS DEVIATION	0371
RAD	RIGHTWARD AXIS	0380
ARAD	ABNORMAL RIGHT AXIS DEVIATION	0381
RSAD	ABNORMAL RIGHT SUPERIOR AXIS DEVIATION	0382
INDAX	INDETERMINATE AXIS	0390
AXIS	THE AXIS	0395
SHFT-LFT	SHIFTED LEFT	0396
SHFT-RGT	SHIFTED RIGHT	0397
LOWV	LOW VOLTAGE QRS, CONSIDER PULMONARY DISEASE, RUH, OR NORMAL VARIANT	0410
PULD	PULMONARY DISEASE PATTERN	0411
S1S2S3	S1-S2-S3 PATTERN, CONSIDER PULMONARY DISEASE, RUH, OR NORMAL VARIANT	0412
RBBB	RIGHT BUNDLE BRANCH BLOCK	0440
RVE+	PLUS RIGHT VENTRICULAR HYPERTROPHY	0441
IRBBB	INCOMPLETE RIGHT BUNDLE BRANCH BLOCK	0445
IRB-RVE		0446
RSR	RSR OR PATTERN IN V1 SUGGEST RIGHT VENTRICULAR CONDUCTION DELAY	0450
LBBB	LEFT BUNDLE BRANCH BLOCK	0460
ILBBB	INCOMPLETE LEFT BUNDLE BRANCH BLOCK	0465
AFB	LEFT ANTERIOR FASCICULAR BLOCK	0470
PFB	LEFT POSTERIOR FASCICULAR BLOCK	0471
BIFBI	(RBBB AND LEFT ANTERIOR FASCICULAR	0478
BIFB2	(RBBB AND LEFT POSTERIOR FASCICULAR BLOCK)	0479
BIFB	***BIFASCICULAR BLOCK***	0480
TRIFB	TRIFASCICULAR BLOCK	0481
IVCD	NONSPECIFIC INTRAVENTRICULAR BLOCK	0482
BO-IVCD	NONSPECIFIC INTRAVENTRICULAR CONDUCTION DELAY	0487
RVH	RIGHT VENTRICULAR HYPERTROPHY	0520
RVH-2ST	RVH WITH REPOLARIZATION ABNORMALITY	0521
LVH	VOLTAGE CRITERIA FOR LEFT VENTRICULAR HYPERTROPHY	0540
LVH2	LVH	0541
QRSV	MINIMAL VOLTAGE CRITERIA FOR LVH, MAY BE NORMAL VARIANT	0542
QRSW	WITH QRS WIDENING	0543
2ST	WITH REPOLARIZATION ABNORMALITY	0544
QRSW-2ST	WITH QRS WIDENING AND REPOLARIZATION ABNORMALITY	0545
LVH3	MODERATE VOLTAGE CRITERIA FOR LVH, MAY BE NORMAL VARIANT	0548
BIVH	BIVENTRICULAR HYPERTROPHY	0570
SMI	SEPTAL INFARCT	0700
SMI-LAE		0701
AMI	ANTERIOR INFARCT	0740
LMI	LATERAL INFARCT	0760
IMI	INFERIOR INFARCT	0780
MAFB	(MASKED BY FASCICULAR BLOCK?)	0782

<u>ACRONYM</u>	<u>INTERPRETATION</u>	<u>CODE</u>
PXT	WITH POSTERIOR EXTENSION	0800
ASMI	ANTEROSEPTAL INFARCT	0810
ALMI	ANTEROLATERAL INFARCT	0820
AC	POSSIBLY ACUTE	0830
INC-MI	INCREASED EVIDENCE OF INFARCTION	0840
DEC-MI	DECREASED EVIDENCE OF INFARCTION	0841
QUE-INICHG	QUESTIONABLE CHANGE IN INITIAL FORCES OF	0842
CRI FOR	CRITERIA FOR	0843
MINI CRIT	MINIMAL CRITERIA FOR	0845
BORD/CRIT	BORDERLINE CRITERIA FOR	0846
MISIZ	***QRS CONTOUR SUGGESTS INFARCT SIZE IS PROBABLY	0880
VSMA	VERY SMALL	0881
SMA	SMALL	0882
MOD	MODERATE	0883
LAR	LARGE	0884
VLAR	VERY LARGE	0885
NST	NONSPECIFIC ST ABNORMALITY	0900
PACARD	ACUTE PERICARDITIS	0901
SERYR1	ST ELEVATION, CONSIDER EARLY REPOLARIZATION, PERICARDITIS, OR INJURY	0902
SERYR2	ST ELEVATION, CONSIDER EARLY REPOLARIZATION	0903
SINJ	SEPTAL INJURY PATTERN	0920
AINJ	ANTERIOR INJURY PATTERN	0930
LINJ	LATERAL INJURY PATTERN	0940
IINJ	INFERIOR INJURY PATTERN	0950
ASINJ	ANTEROSEPTAL INJURY PATTERN	0960
ALINJ	ANTEROLATERAL INJURY PATTERN	0961
REPOL	EARLY REPOLARIZATION	1000
JSTN	JUNCTIONAL ST DEPRESSION, PROBABLY NORMAL	1001
JST	JUNCTIONAL ST DEPRESSION, PROBABLY ABNORMAL	1002
STDIG	ST ABNORMALITY CONSISTENT WITH DIGITALIS EFFECT AND/OR ISCHEMIA	1020
NST2	NONSPECIFIC ST ABNORMALITY	1021
STDEP	ST DEPRESSION, CONSIDER SUBENDOCARDIAL INJURY OR DIGITALIS	1022
SSBINJ	MARKED ST-T ABNORMALITY, POSSIBLE SEPTAL ISCHEMIA	1040
ASBINJ	MARKED ST-T ABNORMALITY, POSSIBLE INFERIOR ISCHEMIA	1050
LSBINJ	MARKED ST-T ABNORMALITY, POSSIBLE LATERAL ISCHEMIA	1060
ISBINJ	MARKED ST-T ABNORMALITY, POSSIBLE INFERIOR ISCHEMIA	1070
ASSBINJ	MARKED ST-T ABNORMALITY, POSSIBLE ANTEROSEPTAL ISCHEMIA	1080
ALSBINJ	MARKED ST-T ABNORMALITY, POSSIBLE ANTERO-LATERAL ISCHEMIA	1081
ST & ST &		1100
ST-NOLDEP	ST NO LONGER DEPRESSED IN	1104
ST-LESDEP	ST LESS DEPRESSED IN	1105

<u>ACRONYM</u>	<u>INTERPRETATION</u>	<u>CODE</u>
ST-MORDEP	ST MORE DEPRESSED IN	1106
ST-NOWDEP	ST NOW DEPRESSED IN	1107
ST-DEPREP	ST DEPRESSION HAS REPLACED ST ELEVATION IN	1108
QUE-STCHG	QUESTIONABLE CHANGE IN ST SEGMENT	1115
ST (INC)	NON-SPECIFIC CHANGE IN ST SEGMENT IN	1116
ST (DEC)	NON-SPECIFIC CHANGE IN ST SEGMENT IN	1117
ST-MORELV	ST MORE ELEVATED IN	1120
ST-LESELV	ST LESS ELEVATED IN	1121
ST-ELVPRS	ST ELEVATION NOW PRESENT IN	1122
ST-NOLELV	ST NO LONGER ELEVATED IN	1123
ST-ELVREP	ST ELEVATION HAS REPLACED ST DEPRESSION IN	1124
NT	NONSPECIFIC T WAVE ABNORMALITY	1140
NSTT	NONSPECIFIC ST AND T WAVE ABNORMALITY	1141
QRST	ABNORMAL QRS-T ANGLE, CONSIDER PRIMARY T WAVE ABNORMALITY	1142
LNGQT	PROLONGED QT INTERVAL OR TR FUSION, CONSIDER MYOCARDIAL DISEASE ELECTROLYTE IMBALANCE, OR DRUG EFFECTS	1143
AT	T WAVE ABNORMALITY, CONSIDER ANTERIOR ISCHEMIA	1150
MAT	MARKED T WAVE ABNORMALITY, CONSIDER ANTERIOR ISCHEMIA	1151
LT	T WAVE ABNORMALITY, CONSIDER LATERAL ISCHEMIA	1160
MLT	MARKED T WAVE ABNORMALITY, CONSIDER LATERAL ISCHEMIA	1161
IT	T WAVE ABNORMALITY, CONSIDER INFERIOR ISCHEMIA	1170
MIT	MARKED T WAVE ABNORMALITY, CONSIDER INFERIOR ISCHEMIA	1171
ALT	T WAVE ABNORMALITY, CONSIDER ANTEROLATERAL ISCHEMIA	1180
MALT	MARKED T WAVE ABNORMALITY, CONSIDER ANTERO-LATERAL ISCHEMIA	1181
T-WAVE	T WAVES	1200
T-INC	T WAVE AMPLITUDE HAS INCREASED IN	1203
T-DEC	T WAVE AMPLITUDE HAS DECREASED IN	1203
LOWT-INV T	FLAT T WAVES HAVE REPLACED INVERTED T WAVES IN	1207
QUE-TCHG	QUESTIONABLE CHANGE IN T WAVES	1208
LOWT-NOL	FLAT T WAVES NO LONGER EVIDENT IN	1210
LESS-FLIT	MORE LEAD EXHIBIT FLAT T WAVES IN	1211
LOWT-NOW	FLAT T WAVES NOW EVIDENT IN	1220
T-INV MOR	T WAVE INVERSION MORE EVIDENT IN	1221
INVT-LOW T	INVERTED T WAVES HAVE REPLACED FLAT T WAVES IN	1222
T-LES INV	T WAVE INVERSION LESS EVIDENT IN	1223
T-INV NOL	T WAVE INVERSION NO LONGER EVIDENT IN	1224
QT-LONG	QT HAS LENGTHENED	1250
QT-SHRT	QT HAS SHORTENED	1251
RAT-DEC	ALTHOUGH RATE HAS DECREASED	1252
RAT-INC	ALTHOUGH RATE HAS INCREASED	1253
WITH-RATING	WITH RATE INCREASE	1254
WITH-RATDEC	WITH RATE DECREASE	1255
QRS	QRS	1419
QRS-DUR	QRS DURATION	1420
QRS-VOL	QRS VOLTAGE	1421
SEP-SEPTAL LEADS		1450

<u>ACRONYM</u>	<u>INTERPRETATION</u>	<u>CODE</u>
ANT	ANTERIOR LEADS	1451
LAT	LATERAL LEADS	1452
INF	INFERIOR LEADS	1453
POS	POSTERIOR LEADS	1454
ANTSEP	ANTERIOR-SEPTAL LEADS	1455
ANTLAT	ANTERIOR-LATERAL LEADS	1456
INFPOS	INFERIOR-POSTERIOR LEADS	1457
PDIG	PROBABLY DIGITALIS EFFECT	1670
ODIG	OR DIGITALIS EFFECT	1671
AHE	ACQUISITION HARDWARE FAULT PREVENTS RELIABLE ANALYSIS, CAREFULLY CHECK ECG RECORD BEFORE INTERPRETING	1674
PO	POSSIBLE	1680
CRO	CANNOT RULE OUT	1682
NML	NORMAL ECG	
ABR	OTHERWISE NORMAL ECG	1687
BO	BORDERLINE ECG	1693
AB	ABNORMAL ECG	1699
SM	SINUS MECHANISM	1701
CMPP	COMPENSATORY PAUSE	1707
ICMPP	INCOMPLETE COMPENSATORY PAUSE	1708
INT	INTERMITTENT	1709
LMKD	LESS MARKED THAN,	1710
PCBD	PACED BEATS	1711
PCDR	PACED RHYTHM	1712
PRU	PROMINENT U-WAVE, SUGGESTING A METABOLIC ABNORMALITY	1713
LGLS	LOWN-GANONG-LEVINE SYNDROME	1714
LQT	PROLONGED QT INTERVAL FOR RATE	1715

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#### IV. Medical Examinations Manuals

##### D. Medical History

###### 1. Introduction

- a. It is the purpose of the history to obtain a complete and accurate medical history from the participant cohort. The medical questionnaire to be used is a complete listing of information which applies not only to the participant, but also to his family.
- b. It is extremely important not to ask the participant about his Vietnam experience exposure. The participant will be informed by the participant advocates not to discuss his exposure with anyone. Although we cannot prevent unwanted information to be volunteered, we can repeatedly inform the participant that we do not wish to know of his perception of his exposure to dioxins. The determination of herbicidal exposure is to be known by the statisticians, not by us. This is extremely important to the physician assistants who will be recording the history.
- c. Preliminary historical information will have been obtained previously during the RTI telephone interview. This information will become part of the participant's history record at CDC, but will not be available for use at Lovelace. The major historical information needed for diagnostic purposes at Lovelace will be obtained during the 30 minute history taken on Medical Exam Day. This history also serves the purpose of providing information on health-related events that may have occurred during the time interval between the telephone interview and the participant's arrival in Albuquerque. All questions must be asked. There may be circumstances when the participant will not wish to answer a question. If it is felt that an explanation of the reasons behind asking the question will help in assuaging the participant's objections, then such an explanation should be given. If it appears that the participant will not answer the particular question under any circumstances, then the refusal to answer should be so coded.
- d. The total number of questions asked, and responses entered, for any individual participant will differ based on the responses given to particular questions. Should a participant respond affirmatively to a particular question, a more detailed or comprehensive set of questions will follow. In the case of a negative response, the questioner will go on to the next general question. It is incumbent upon the questioners to be familiar not only with the usual questions asked, but also those less frequent default responses which may arise in the course of questioning.

- e. Before beginning the set of specific history questions, an introductory statement is read to the participant. The interviewer should present this and subsequent questions in a friendly, relaxed manner. A forward leaning or slouching posture should be avoided. The interviewer should also explain to the participant that he will be entering answers directly onto the data collection form during the interview.

## 2. Procedure

- a. The Medical History questionnaire will be administered and data collected through an interactive procedure with the participant. All responses, both free text and coded, will be entered as the participant responds. This procedure will provide the most accurate and immediate capture of the needed information. In the event there are multiple responses and/or additional information, this will be written in longhand and attached to the hard copy.
- b. The following specific procedures will be followed for the collection and reporting of medical data:
  - (1) At the beginning of the day, the day's scheduling report will be distributed to the physician's assistant (PA). This report will list each participant who is to have a history taken for the day. The report does not list the participants in the order to be interviewed, however, it does show the schedule number (1-23) that the participants have been assigned.
  - (2) The scheduled participant will arrive.
  - (3) The PA will check off the participant on the daily schedule. This will provide an ongoing record of participants who have or have not been interviewed.
  - (4) The PA will enter the medical record number assigned to the participant, the participant's name, the date, PA/NP's ID# and the interview start time onto the medical history form.
  - (5) The PA will begin administering the questionnaire, reading the questions and/or statements. Questions that do not apply will be skipped. As the participant responds, the PA will enter the appropriate code or text. All coding appears on the form to facilitate an efficient entry process. For responses too large to fit in the allocated space, the PA will be required to abbreviate the participant's response in order to make the text fit.
  - (6) The PA will proceed through the entire questionnaire. At its completion, the PA will enter the completion time, and the questionnaire status.

- (7) The PA will review the printed interview form. If errors are found, he/she will go to the appropriate incorrect answer and correct it.
- (8) Once the PA is satisfied with the accuracy of the interview, he/she will verify by signing it.
- (9) After the participant leaves, and prior to the next one arriving, the PA will complete the Participant Responsiveness Questionnaire.
- (10) The PA will take the printed interview and the Responsiveness Questionnaire to the Medical Records Specialist's office and place them in the appropriate result slot.
- (11) The PA is now ready for the next participant and will continue with steps 3-10 until all participants for the day have been interviewed.
- (12) After all participants have been interviewed, the daily schedule should be taken to the Clinic Manager and filed.

### 3. Supervision

The Clinic Manager will oversee and coordinate the daily flow of the participants and clinical personnel, as necessary.

### 4. Quality Control

- a. The Clinic Manager will monitor the performance of the PAs in the following manner:
  - (1) Once per day, the Clinic Manager will listen to a history as it is being taken, using microphones connecting the Clinic Manager's office with the offices used by the PAs.
  - (2) She will record the participant's answers on a history data collection form as they are given. This form will go to Data Processing for key taping along with the data recorded by the PA.
  - (3) The two sets of data will be compared for correspondence of answers at CDC.
  - (4) The Clinic Manager will make comments regarding skipped questions, misread questions or inconsistency in presentation on a separate form.
  - (5) Documentation of the quality control observation and any problems observed will be made on an appended form.

### 5. Backup Personnel

The Clinic Manager will maintain a backup list of physician assistants who will be certified as trained by the

Clinical Manager and who can be pulled from their regular responsibilities to cover for unexpected absences. Repeated absences by the physician's assistants will result in disciplinary action in accordance with the LMF's policies.

6. Participant Delay

Certain instances will invariably occur when the schedule is delayed such that the participant is late in starting his schedule. If this delay is part of a specific circumstance that affects all of the participants, the entire schedule will be adjusted accordingly. In the event of a particular participant failing to be present for a particular session, an attempt will be made to obtain the information at an alternate time if it can be scheduled without further disruption. In the event of repeated tardiness on the part of the participant, the Clinic Manager will determine whether the participant will be allowed to continue the other portions of the evaluation.

7. Subject Problems

If, during the course of testing, a participant decides to terminate or refuse the history questionnaire, the Clinic Manager will be notified. The participant then will be reminded of the importance of completing the questionnaire, recognizing that the individual has the right to refuse. If the participant, at that time, still decides not to continue the questionnaire, a refusal will be entered into his record.

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#### IV. Medical Examination Manuals

##### E. Hypersensitivity Skin Testing

###### 1. Introduction

The purpose of hypersensitivity skin testing is to assess cell-mediated immunity (delayed cutaneous hypersensitivity). The testing method is by multitest, multipuncture, which tests for response to tetanus, diphtheria, streptococcus group C, tuberculin, Candida albicans, Trichophyton, Proteus, and a glycerin control. Skin tests are applied by the registered nurses and reactions are read by a technician 48 hours after application. CMI readings take place at the hotel during the exit interview sessions. Data are recorded on a form, which is forwarded by Medical Records personnel to Veterans' Health Study Data Processing for data entry.

###### 2. Equipment

The multitest cell-mediated immunity (CMI) consists of an applicator of acrylic resin preloaded with seven antigens and one control. Each multitest CMI head contains one drop of antigen in a glycerin solution to 70% weight/volume.

a. Tetanus antigen	550,000 Merieux units/ml
b. Diphtheria antigen	1,100,000 Merieux units/ml
c. Streptococcus group C antigen	2,000 Merieux units/ml
d. Tuberculin, old antigen	300,000 I.U. ml
e. Glycerin control: glycerin solution	70% weight/volume
f. Candida albicans antigen	2,000 Merieux units/ml
g. Trichophyton mentagrophytes antigen	150 Merieux units/ml
h. Proteus mirabilis antigen	150 Merieux units/ml
i. Alcohol swabs	

###### 3. Procedure

- a. Remove Multitest CMI from the refrigerator at least one hour before use.
- b. Multitest CMI should be applied only on healthy skin. Preferred application sites are the volar surfaces of the forearm, or the back, or the anterior surface of either thigh. First, disinfect the area with ethyl alcohol and allow to dry.
- c. With the protective film face up, tap the bar of the Multitest CMI on a hard surface several times to ensure that the lines are bathed with antigens.
- d. Gently remove the protective film from the unit .
- e. Holding the unit firmly, remove each protective cap from its corresponding head with a gentle twisting motion.

- f. Place the participant's arm on a flat surface. Hold the skin taut at the application site.
- g. Pointing T-Bar end of unit toward participant's head, apply VERY FIRMLY. To ensure even penetration, press FIRMLY for at least 5 seconds. Being careful not to lift the test heads from the skin, rock the unit back and forth and side to side.

Proper procedure is confirmed by observing each of the following:

- (1) A circular imprint of the platform from each test head.
  - (2) Puncture marks of the nine tines of each test head (a square-shaped pattern).
  - (3) Residual liquid at each test site.
- h. Allow liquid to remain on the skin for a least 3 minutes so that antigens may penetrate.
  - i. Gently blot all test sites with sterile gauze, being careful not to smear and cross-contaminate test sites.
  - j. Mark the upper and lower limits of the application site with an indelible marker.
  - k. Discard the Multitest CMI unit. It must never be used a second time.

#### 4. Reading CMI

Reading is done at 48 hours as follows:

- a. By palpation, verify induration to be measured for each reaction. (Erythema alone is not a reliable indicator.) Circle the indurated surfaces with a pen or draw a line until you feel the pen meet the edge of the induration on four sides.
- b. For each reaction, measure average diameter with the Multitest caliper or a small-scale ruler.
- c. A reaction is considered positive if the average diameter is 2 mm or greater.
- d. Negative (<2mm) reactions are scored as zero.
- e. Record the measurement of each induration on the record sheet.

NOTE: The negative control serves to ensure that the participant is insensitive to the glycerin used for suspending each of the antigens. Use it as a comparison for the positivity of weak reactions.

- f. The antigen score is the number of positive reactions out of a possible seven.
- g. The total induration score, expressed in millimeters, is the sum of the average diameters measuring ( $\geq 2$ mm; e.g., 21mm).
- h. The combined score expresses the antigen score over the total induration score.
- i. The score established by Multitest CMI directly reflects the participant's level of CMI function. It can identify:
  - (1) Anergic (nonresponding) subjects.
  - (2) Weakly responding or hypoergic subjects.
  - (3) Subjects responding within normal limits.
- j. Change in the score is a sensitive monitor of change in CMI status over time. Due to its reproducibility and failure to sensitize, Multitest CMI is ideal for taking serial readings to help establish diagnosis, prognosis, or response to therapy.

#### 5. Side Effects

Presistence of a slight erythematous reaction for 3 to 10 days. In highly sensitized subjects the local reaction may be considerable for one or more of the antigens and may take on a blistered or ulcerated appearance. Local pain or pruritus may be alleviated by the application of glucocorticoids or ice pack.

#### 6. Caution

This test cannot, by itself, provide a complete evaluation of the state of immunity. This product should be used only by a physician or someone under his/her direct supervision.

The reaction to the various antigens can be temporarily reduced or disappear following a febrile illness (measles or other viral illness), the administration of live viral vaccines (e.g., measles vaccine), treatment by corticosteroids or other immunosuppressants.

#### 7. Supervision

The Clinic Manager will oversee the hypersensitivity testing with overall supervision by the Medical Director. Initial training and periodic retraining of nurses and technician-readers is performed by a representative of the Merieux Company, manufacturers of the Multitest CMI. Nurses and readers are periodically observed by the Clinic Manager.

## 8. Quality Control

Internal quality control for the multitest CMI kit is a glycerin control and sterile water solution. The Clinic Manager will observe administration of one random test per day, and the Special Assistant for Quality Control and Scientific Affairs will do repeat blind readings on six randomly chosen tests per week. Data from blind readings should correspond with the original reading in the following manner. All reactions should have been read correspondingly as either positive or negative for both readings, and measurements for positive reactions should be within 1 mm. Discrepancies will be resolved by identifying the technician doing the original reading, and having the clinic nurses or Clinic Manager observe readings with the technician and the "blind" reader, to assure consistency in the manner of reading. In case of persistent inconsistencies in reading, the Merieux Company's representative will be asked to retrain all readers.

## 9. Subject Problems

### a. Allergic Reactions

In the event of an immediate or delayed allergic reaction, qualified personnel will have an emergency medical cart at their disposal. The following drug reaction protocol will be initiated by the Clinic Manager, or by the clinic nurses with the knowledge of the Clinic Manager.

- (1) In the event of an anaphylactic reaction, immediate treatment with epinephrine is imperative. It is a pharmacologic antagonist to the effects of the chemical mediators on smooth muscle, blood vessels, and other tissues.
- (2) For mild reactions such as generalized pruritus, urticaria, angioedema, mild wheezing, nausea, and vomiting, 0.3 to 0.5 ml of aqueous epinephrine 1:1000 should be given subcutaneously. A tourniquet should be applied above the injection site and 0.1 to 0.2 ml of epinephrine 1:1000 also injected into the site, in order to reduce systemic absorption of the antigen. This may suffice for a mild reaction, although a second injection of epinephrine subcutaneously may be required. Once symptoms have resolved, an oral antihistamine-ephedrine combination should be given for 24 hours.
- (3) For more severe reactions, with massive angioedema but without evidence of cardiovascular involvement, participants should be given diphenhydramine 50-100 mg intramuscularly (for an adult) in addition to the above treatment, to forestall laryngeal edema and to block the effect of further histamine release. When the edema is

responding, 0.3 ml of susphrine 1:200 subcutaneously can be given for its 6-8 hour effect, and an oral antihistamine-ephedrine combination should be given for the next 18 hours.

- (4) For severe respiratory reactions that do not respond to epinephrine, IV fluids should be started and aminophylline 6 mg/kg IV should be given over 10-20 minutes, followed by 1 mg/kg/h. Endotracheal intubation or tracheostomy may be necessary, with oxygen administration at 4 to 6 L/min.
- (5) Participants with severe reaction should remain in a hospital under observation for 24 hours following recovery to ensure adequate treatment in case of relapse.

b. Participant Refusal

If, during the course of testing, a participant decides to terminate or refuses the hypersensitivity test, the Clinic Manager will be notified. The participant then will be reminded of the importance of completing the test, recognizing that the individual has the right to refuse. If the participant at that time still decides not to continue the test a refusal with the signatures of the participant and the Clinic Manager will be entered into his record.

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#### IV. Medical Examination Manuals

##### F. Nerve Conduction Velocity

###### 1. Introduction

- a. The procedures outlined in this manual are designed to be used in concert with a clinical neurological exam to detect the presence of peripheral neuropathy. The electrophysiological measures include assessment of both sensory and motor fibers and specifically target the distal nerve segment of both the upper and lower limbs. Dysfunction in these regions is characteristic of a number of peripheral neuropathies including those associated with exposure to exogenous neurotoxins.
- b. Each discussion reviews the relevant anatomy, lists applications, describes the technique, and provides a referenced table of normal values. Every technique is described step by step, and is illustrated with drawings.

###### 2. Equipment

- a. TECA TD10 MK1 with:
  - (1) Two channel differential amplification
  - (2) Averaging capability
  - (3) Internal cursor for time and amplitude measurements
  - (4) Stimulus isolation unit for generation of electrical pulses
  - (5) Preamplifier Box
  - (6) Skin Electrodes
  - (7) Stimulator
  - (8) Ground
  - (9) Ring Electrodes
  - (10) Foot Pedal
  - (11) Recording Paper
- b. Reclining chair
- c. Skin Thermometers
- d. Omni-Prep (alcohol/acetone swabs if unavailable)
- e. Electrode Gel
- f. Tape (transparent or surgical, etc.)
- g. Tape Measure (with centimeter measurements)
- h. Gauze Wipes (4x4's, 2x2's)
- i. Electrode Covers
- j. Cotton-Tipped Applicators
- k. Pre-printed Result/Recording Sheet

Further explanations and more detailed information on the TD10 MK1 machine as it pertains to this study are included in the following pages.

### 3. TECA TD10 MK1 Control Settings

#### a. Mode

The MODE switch has three positions for NCV testing: ACQ, RUN and EXT.

##### (1) ACQ

The position labeled ACQ will allow the TD10 MK1 to deliver stimulus to the patient only during the period of time that motor or sensory responses are being acquired from the participant.

##### (2) RUN

Stimulus will be presented continuously to the participant.

##### (3) EXT

Stimulus will be controlled by an external device.

#### b. Duration

This control selects the duration of the stimulus from 0.05 to 0.5 ms for both SINGLE and DOUBLE stimuli. Normally SINGLE stimuli at 0.05 or 0.1 ms is selected.

#### c. Rep Rate

Normally a rate of 1 pps is selected, 3 pps for repetitive (MULTISTIM).

#### d. Intensity

Start at 0 and increase, as desired, after operating the ACQUIRE switch.

#### e. Filter

The FILTER switch has three positions useful for NCV work. They are EMG 1:2Hz to 10kHz, EMG 2:20Hz to 10kHz and SCV:20 Hz to 2kHz.

(1) EMG 1 is the setting normally used for motor conduction testing.

(2) EMG 2 is an optional setting sometimes used for motor nerve conduction testing.

(3) SCV is setting normally recommended for sensory nerve conduction testing.

f. Volts/Div

The VOLTS/DIV control for Channel 1 is set normally to 2 mV or 5 mV for motor conduction testing and to 10 uV for sensory nerve conduction testing. 100 uV for F wave and H response testing.

g. Time/Div

The TIME/DIV control selects the time base or sweep speed in milliseconds per division. For NCV, 2 ms is normally selected, 10 ms for F wave and H response testing.

h. Acquire

There are three ways to acquire data (muscle or nerve potentials) when the MODE switch is in the ACQ position to provide stimulus for these responses.

- (1) While the system is acquiring data, the display will show a stored (FROZEN) response from the previous stimulus. With each additional stimulus, the old response will be discarded and the new response will take its place.
- (2) Push the ACQUIRE switch up to acquire new responses and return the ACQUIRE switch to its center position to cease acquiring additional responses.
- (3) Push and hold down the ACQUIRE switch to acquire responses and release the ACQUIRE switch to cease.
- (4) Press down and hold down the footswitch to acquire responses and release the footswitch to stop.

i. LOAD 1, LOAD 2 and Cascade Buttons

The operation of one or two of these buttons will control the number of input channels and which display trace is in operation. The Channel 1 amplifier and preamplifier are always in operation.

- (1) LOAD 1: All signals from Channel 1 will be displayed on the upper trace.
- (2) LOAD 2: All signals from Channel 1 will be displayed on the lower trace.

j. Cascade

In this mode all acquired signals will be presented first on the upper trace, then on the lower trace as follows: Stimulus one: The response is stored on the upper trace. Stimulus

two: The response from stimulus one is cascaded from the upper trace to the lower trace and the response from stimulus two is stored on the upper trace. With each additional stimulus, the displayed responses are cascaded through the traces with the most recent response always displayed on the upper trace.

#### k. Cursors

Description: Two cursors are available. Each of these appears as bright dots and are presented on both the upper and lower traces. The latency of CURSOR 1 can never exceed the latency of CURSOR 2. The movement of these cursors is controlled by five buttons, two for CURSOR 1 and two for CURSOR 2, with a fifth button to speed up the movement of either cursor. The latency is indicated by a four-digit LED display to the right of the CRT display marked, SWEEP, CURSORS, in ms. Below the LED readout are three buttons for Time 1 (T1), Time 2 (T2) and the difference between Time 2 and Time 1 (T). The cursors will appear any time one of these eight buttons is pressed. If T has not been pressed, operating CURSOR 1 will result in T1 (Time 1) latency being displayed on the four-digit LED display and operating CURSOR 1 will make the LED display show the latency of its cursor. The same applies for CURSOR 2. If T has been pressed, the LED display will always show the latency difference between the two cursors. To read latency of one of the cursors again, press either T1 or T2. The cursors will automatically disappear if not used after approximately 50 seconds. All the buttons that involve the cursors are blue.

#### 4. TECA TD10 MK1 Operation

##### a. Latency Measurements

- (1) Measurement of the latency of two responses as displayed, one on each trace of the CRT display is accomplished as follows. Operate CURSOR 1 by pressing either of its two buttons marked  $\lambda$  or  $\mu$ . If the button is held down steadily, the cursor will first step slightly in the appropriate direction then pause for one second. If the button is still held in, the cursor will again start to travel in the correct direction and continue until the button is released. Move CURSOR 1 until it is close to the take off of the response with the shorter latency. When the cursor is close to the correct point, it can be moved in small steps by tapping the correct cursor button. Note that the LED above T1 will be lit. Read the latency of CURSOR 1 as indicated by the four-digit LED display above.
- (2) Now use the CURSOR 2 buttons in the same way to place the second CURSOR at the take off of the response on the other trace. Observe that the LED above T1 is out and the LED above T2 is now on indicating the four-digit LED display above is indicating the latency of the second CURSOR.

b. Averaging

- (1) The TD10 MK1 has two averagers internally, AVG A and AVG B. They can be operated independently or simultaneously. They will operate in any mode except REAL TIME FREE. There are three buttons (all yellow) that control the operation of these averagers.
- (2) Apply the pickup electrodes and stimulator electrodes to the participant. Select either AVG A or AVG B. While observing the four-digit LED display to the left of the CRT, increase the gain of Channel 1 until the maximum sensitivity possible has been reached. The appearance of four dots in the four-digit LED display indicates that you have reached that point. If the dots are flashing on and off, but are off 80% or more of the time, the gain setting is okay. However, if the dots are on for a period of time, greater than 20% of the time, the sensitivity control should be set to the next lower (larger number) sensitivity setting. If the four-digit LED display (Averager Sweeps) indicates anything other than 0, press the ERASE button. To start averaging, operate the ACQUIRE switch. Return the ACQUIRE switch to its center position to stop averaging. The DISPLAY GAIN control will change the size of the display on the lower trace by magnifying the display of the averager's memory. The DISPLAY GAIN may be changed while the test is in progress. The OFFSET buttons will shift the lower trace up and down. The number of sweeps averaged will be indicated by the four-digit LED AVERAGER Sweeps display.
- (3) The ERASE button will erase the averager memory. Selecting AVG B by pressing the AVG B button will change the display of the lower trace from AVG A to AVG B. Any information stored in AVG A will not be lost. AVG B is now available and is operated the same way as AVG A. If after you have stored information into both averagers, it is possible to display both averager memories simultaneously; to do so, press the AVG A&B button. The upper trace will be AVG A and the lower trace will AVG B.
- (4) After applying the stimulating and pickup electrodes, connecting the electrodes to the TD10 MK1, and switching both preamplifiers to PAT, set the mode to ACQ and press the AVG A&B button twice. The LED above the AVG A&B button should be flashing. Both traces should be displaying incoming participant data. Set both Channel 1 and Channel 2 GAIN controls as described in single-channel operation manual. To observe the averager's memories, press the AVG A&B button. Every time this button is pressed, the display will change between incoming data and averaged data. The LED above the AVG A&B button will flash when the display is

incoming data and will be continuous while the display is showing averaged data. This control may be operated while averaging to allow the operator to switch the display between the two functions without affecting or stopping the test in progress. To start and stop the averager, use the ACQUIRE switch. The Averager Sweep's four-digit LED display will show the number of samples averaged and when the four dots appear, indicate that the incoming signal is too large to be averaged and is being rejected (artifact reject). The magnification of the averager memory may be changed at any time without affecting the test by changing the DISPLAY GAIN. The upper trace may be shifted up and down with the OFFSET buttons. To shift the lower trace, press and hold the FAST button while operating the OFFSET buttons.

c. Making Records

- (1) The TD10 MK1 can plot both the upper and lower trace of the CRT. All records are fully identified as to record number, the sensitivity as displayed on the record, and the sweep time as displayed on the record, all at the time the recording was made. Additional information recorded (depending upon the test mode) will be, expanded sweep, number of sweeps, sweep delay, sum or difference of 2 averages, latencies (T1 & T2) and voltage difference between markers, percent of reject with percent of change in area between the first and fourth, first and ninth response in a multiple stim test.
- (2) To make a recording, press PLOT 1 for recording the upper trace; PLOT 2 to record the lower trace. Pressing the SPACE button will advance the paper approximately 12 cm. This is to prevent you from tearing the last record in half. Holding in the FAST button and simultaneously pressing either PLOT 1 or PLOT 2 will record either trace with the latency markers and identify the latencies of T1, T2 and the amplitude difference between the two markers. Each trace contains a minimum of the following information (Reference Diagram 2.3.A). The arrow (N) identifies the start of the trace. The first number identifies the record number. This number is reset to 1 every time the instrument is turned off. The (Ch) indicates the channel that was used, not the trace. The amplitude sensitivity is indicated next for two major divisions vertically. Next, the sweep time is shown for two major divisions horizontally. And last, a four-digit code to identify major control settings at the time of the test.

d. Traces

- (1) Single Trace: Press PLOT 1 or PLOT 2 for upper or lower trace.

- (2) Single Trace with Markers: Press and hold FAST, simultaneously press either PLOT 1 or PLOT 2.

e. Special Functions

- (1) The TD10 MK1 performs a wide range of special functions. However, all these special functions are not obvious from looking at the front panel. To use any of these special functions, you must press two buttons simultaneously. First, press FAST and while holding the FAST button in, press a second button. The FAST button tells the computer inside the TD10 MK1 that you want the second button to perform a second or alternate operation. There are four exceptions that do not require the use of the FAST button.
  - (a) Repetitive or multi stimulation: Press LOAD 1 & LOAD 2. Available in the ACQ mode only.
  - (b) Display averager A and B after two sequential single channel runs. Press AVG A&B.
  - (c) Press AVG A&B. The AVG A & B LED will flash in the raw data display mode.
  - (d) Move the CURSORS at double their normal speed. Press FAST and one of the four CURSOR buttons.

f. Special Function Summary

- (1) FAST & PLOT 1: Records trace 1 with markers.
- (2) FAST & PLOT 2: Records trace 2 with markers.
- (3) FAST & OFFSET: Shifts trace 2 with both averaged channels displays.
- (4) FAST & CURSOR: Doubles cursor movement speed.
- (5) FAST & LOAD 1: Smooths trace 1.
- (6) FAST & LOAD 2: Smooths trace 2.
- (7) FAST & AVG A: AVG A + AVG B.
- (8) FAST & AVG B: AVG A - AVG B.
- (9) FAST & AVG A&B:  $(AVG A + AVG B)/2$  on trace 1.
- (10)  $(AVG A - AVG B)/2$  on trace 2.
- (11) FAST & SUPERIMPOSE followed by AVG A&B: Transfers display from trace memories to averager memories.

- (12) FAST & T1: Implements Amplitude measurement trace 1.
- (13) FAST & T1: Implements Amplitude measurement trace 2.
- (14) FAST & T: Exits Amplitude measurement mode.
- (15) T & PLOT 1: Plots on XYP2 Plotter trace 1.
- (16) T & PLOT 2: Plots on XYP2 Plotter trace 2.
- (17) LOAD 1 & LOAD 2: (ACQ mode only) Multistim.

#### 5. Maintenance

Maintenance of the TD10 MK1 includes a daily calibration due to the amount of use the machine will receive. A calibration and maintenance service record will be maintained on each machine. For further information, please see the Equipment Manual.

##### a. To change expendable paper:

- (1) Open the paper loading carriage, pulling forward the finger grip on the right hand side.
- (2) Remove the core of the old roll from the spindle.
- (3) Free the end of the new roll and slide the roll onto the spindle.
- (4) Unroll a convenient length of paper, carry the end over the knife edge of the carriage, and close.
- (5) Depress SPACE and insert the end of the paper into the top of the drive roller.
- (6) Run a sufficient length of paper to check the feed.

##### b. Calibration and Corrective Maintenance

This instrument was calibrated when it left the factory and, under normal circumstances, needs no further calibration.

- (1) To verify the TD10 MK1 or calibration, set the controls as follows:
  - (a) Mode to AMP CAL
  - (b) FILTER to EMG 1
  - (c) REP RATE to 10
  - (d) TIME/DIV to 1
  - (e) VOLTS/DIV to 500,
  - (f) Both Preamplifier switches to CAL
  - (g) Press LOAD 1 on TD10 MK1

- (h) Push the ACQUIRE switch up
- (i) One trace on the TD10 MK1 should display a two-division high calibrate step in the middle of the CRT display
- (j) Plot Trace 1 and Trace 2
- (k) Then check the record and verify the amplitude of the recorded traces

## 6. Specific Test Procedures

### a. Nerves and End Points To Be Assessed:

- (1) Median Motor (orthodromic)
  - (a) NCV of forearm segment
  - (b) M-wave amplitude
- (2) Peroneal Motor (orthodromic)
  - (a) NCV of distal segment (knee to ankle)
  - (b) M-wave amplitude
- (3) Median Sensory (antidromic)
  - (a) NCV of forearm segment
  - (b) NCV of distal segment (wrist to interdigital cleft)
  - (c) Amplitude of compound sensory response
- (4) Ulnar Sensory (antidromic)
  - (a) NCV of distal segment (wrist to interdigital cleft)
  - (b) Amplitude of compound sensory response
- (5) Sural Sensory (antidromic)
  - (a) NCV segment from mid-calf to ankle
  - (b) Amplitude of compound sensory response
- (6) All electrophysiological procedures should be performed unilaterally and on the same side for both upper and lower limbs. The dominant limb should be used unless contraindicated by localized pathology (e.g., injuries, history of entrapment, etc.).
- (7) Motor nerve conduction velocity (NCV) is defined as the difference in onset latency (the time in milliseconds from the stimulus artifact to the recorded response) of the M-wave response following stimulation at a proximal and distal site, divided into the distance between the stimulating cathodes. Sensory NCV can be calculated in a similar manner or by using the absolute latency of the initial negative component of the sensory response divided into the distance between the stimulating cathode and the active recording electrode. The amplitude (the depth) of the deflection from the baseline to the peak, of all components is measured from the baseline (pre-stimulus if available) to the peak of the component.

## b. Methods

### (1) Electrodes

All stimulating and recording electrodes should be applied to the skin surface. Ring electrodes, which encircle the finger, are recommended for median sensory and ulnar sensory nerves.

- (a) Clean the skin with a suitable solvent, e.g., Omni-Prep, acetone.
- (b) Lightly abrade the skin with electrode paste.
- (c) Apply a conducting medium, e.g., electrode jelly, between the electrode and the skin.

### (2) Skin Temperature Control

Skin temperature should be maintained at 33.0 °C, (32-36 degrees for upper extremities and 31-35 for lower extremities plus or minus 1 °C, throughout testing. Skin temperature should be measured prior to testing at sites mid-way between the stimulating and recording electrodes for each limb. Temperature should be monitored and adjusted during testing using one of the following procedures:

- (a) a warm water bath
- (b) a temperature-controlled blanket wrap

### (3) Computer Averaging

All measurements should be taken from a computer averaged signal using internal cursors. This averaging technique will enhance the signal to noise ratio and facilitate accurate measurement of response onset. When measuring the M-wave response averaging 3 to 5 stimuli should be sufficient, whereas for the sensory response between 5 and 32 stimuli should be averaged.

### (4) Stimulation

- (a) All testing should be done with the subject carefully isolated from ground using a professional stimulus isolation unit. Stimulus intensity varies as a function of the specific nerve and site of stimulation; the intensity should be adjusted according to the guidelines below.
- (b) Orthodromic stimulation refers to the usual direction of impulse conduction along a nerve: the direction is from distal to proximal along a sensory nerve or from proximal to distal along a motor nerve. Antidromic

refers to the direction opposite physiological conduction along a nerve. Motor nerve conduction studies are performed orthodromically (stimulate proximally, record distally) whereas sensory studies can be performed either orthodromically (stimulate distally, record proximally) or antidromically (stimulate proximally, record distally).

(c) We will use antidromic stimulation for sensory NCV's - for the present testing.

(5) Stationary Standard Settings for Testing a Participant:

- (a) Mode in acquire
- (b) Stimulator duration 0.2
- (c) Rep rate 1
- (d) Preamp in PT
- (e) Filter in: EMG 1 for muscle response
- (f) SCV for sensory response

(6) Variable Settings for Testing a Participant:

- (a) Time division start at 2
- (b) Volts division m, MV 5 for motor, and UV 10 for sensory for starting
- (c) Intensity starting setting at 100 and increase to reach supra-maximal response

c. Motor Studies

Motor nerve measurements involve stimulating an accessible nerve and recording the evoked muscle action potential (EMAP) from an appropriate muscle. In motor nerve conduction studies it is necessary to use a supramaximal stimulus, (the maximal response obtained by increasing the intensity and receiving equal responses on the screen). To ensure a supramaximal stimulus the voltage should be increased to at least 25 percent greater than that above which no increase in amplitude of the EMAP is seen. In the determination of motor latencies, the onset of the initial negative (downward) deflection from the baseline is the point that determines latency. The amplitude is measured from the baseline to the peak of the negative deflection. (The anode is always placed distal to the cathode for stimulation.)

(1) Median Motor (Orthodromic)

(a) Anatomy

The median nerve serves mainly as the motor nerve to the radial side of the flexor portion of the forearm and the muscles of the upper palm above the thumb and

as the sensory nerve to the radial (lateral) palmar surface including all or part of the palmar surfaces of the first four digits. The median nerve receives fibers from C 6,7,8, and T1, which pass through the upper, middle, and lower trunks of the brachial plexus into the lateral and medial cords, the terminal portions of which merge to form the median nerve. The median nerve then descends in the upper arm in close proximity to the brachial artery and finally traverses the midventral aspect of the forearm to the tunnel under the flexor retinaculum (carpal tunnel) from which it emerges to innervate the LOAF muscles of the hand (first and second/umbricals, opponens pollicis, abductor pollicis brevis, and flexor pollicis brevis).

(b) Applications

The median nerve is commonly entrapped in the carpal tunnel. It is less frequently involved in the pronator syndrome, anterior interosseous syndrome, and the ligament of Struther's syndrome. Rarely, compression of the brachial plexus in the thoracic outlet may involve nerve fibers that ultimately join the median nerve.

(c) Procedure--DISTAL

- (i) Position the active recording electrode over the motor endplate of the abductor pollicis brevis (at the thumb side of the palm).
- (ii) Position the reference ring electrode on the same thumb at least 2.0 cm distal to the active lead.
- (iii) Place the ground between the distal stimulation site and the active recording lead, medial to active electrode (belly of palm on little finger side).
- (iv) The distal and proximal stimulation sites are identical to those used for median sensory stimulation (over median nerve between radial and ulnar nerves and above elbow crease just beneath bicep definition). Stimulus duration should be 0.2 msec. Time/Division should be at 2. Pre-amplifier should be at "Patient". Volts/Division should be at 5 on the motor side (mV). EMG I, Rep. Rate 1, with a stimulus rate of 1 per second.

(v) Measure onset latency (Cursor #1) from beginning of baseline to beginning of deflection (milliseconds) (cursor #2) and record.

(vi) Measure amplitude (cursor #1) from beginning of deflection to peak then push "Fast" and "T1 or T2" simultaneously and record.

(d) Procedure--PROXIMAL

(i) Leave ground disk, reference ring and active electrode same as for distal placement; superimpose for supramaximal response; measure onset latency - record, and measure distance between stimulating sites (mm).

(ii) The average motor conduction velocity in the upper extremity is 60 m per second and the average motor conduction velocity in the lower extremity is 45 m per second. Values in the newborn are about one-half those of the adult, reaching adult values at the age of four years.

(iii) Normal Values (Motor)

Segment	Distal Latency or NCV	Amplitude (mV)
Wrist to abductor pollicis brevis	3.9 ± 0.37 (3.4-4.5) msec	11.8(7-17)
Elbow to wrist	49.0 ± 3.9 (45.1-54.4) m/sec	11.8(7-17)

Lower limits of normal values

Median Motor

NCV	50 m/sec	
M-wave amplitude		4.5

(2) Peroneal Motor (Orthodromic)

(a) Anatomy

The common peroneal nerve and the tibial nerve are the two terminal divisions of the sciatic nerve. The common peroneal nerve is composed of fibers from L4, L5, S1, and S2. It runs laterally in the popliteal fossa, close to the medial border of the biceps femoris. It travels to the neck of the fibula, around which it winds, and then divides into the superficial and deep peroneal nerves. The deep peroneal nerve joins the anterior tibial artery in the proximal leg and then parallels

this artery, passing under the extensor retinaculum and dividing into terminal medial and lateral branches at the ankle. The lateral terminal branch supplies the extensor digitorum brevis muscle; more proximal branches innervate the extensor muscles of the foot and toes. The peroneus longus and peroneus brevis are innervated by branches of the superficial peroneal nerve.

(b) Applications

The common peroneal nerve is vulnerable to compression where it becomes superficial over the lateral aspect of the neck of the fibula. Injury to the peroneal nerve at this level causes impaired dorsiflexion and eversion of the foot and may also cause pain or paresthesias along the lateral surface of the leg, although the sensory fibers are less vulnerable to damage. In compression palsy of the common peroneal nerve, slowing may be present only in the segment across the head of the fibula. Therefore, a conduction velocity measured from the popliteal fossa to the ankle may fall within the normal range. To diagnose localized compression, the conduction velocity across the head of the fibula should be more than 10 m per second slower than values recorded distal to the fibula. The common peroneal nerve is also often involved in generalized neuropathies such as those caused by uremia and diabetes mellitus.

(c) Procedure--DISTAL

- (i) Place the active recording electrode over the endplate area of the extensor digitorum brevis, (lateral just forward of ankle bone).
- (ii) Place the reference on the lateral surface of the same foot at the base of the fifth digit.
- (iii) Place the ground on the midline at the level of the ankle.
- (iv) When stimulating at the ankle, position the cathode over the peroneal nerve 8.0 cm proximal to the active recording electrode.
- (v) Stimulus duration should be 0.1 or 0.2 msec.
- (vi) Stimulus intensity should be adjusted to elicit a brief twitch of the extensor digitorum brevis and should be supra-maximal for M-wave amplitude.
- (vii) Stimulus rate should be 1 per sec.

(viii) Volts/Div. to 5/9 motor side mV); filter to EMG I.

- (ix) Intensity - start at 100;  
Stimulate - check with participant where stimulation was felt (should be felt toward midline ventral surface);  
"Superimpose" for supramaximal response and measure onset latency and amplitude (to record amplitude push "Fast and T1 or T2" simultaneously).

(d) Procedure--PROXIMAL

(i) When stimulating at the knee, position the cathode overlying the peroneal nerve, slightly distal and lateral to the head of the fibula.

(ii) All electrodes remain unchanged;  
stimulate - measure onset latency, and measure distance between stimulator sites (1m).

(iii) Normal Values

Segment	Distal Latency or NCV	Amplitude (mV)
Ankle to EDB	5.1 msec	8.8 (6-14)
Proximal to head of fibula to ankle	50 (SD 3.5) m/sec	8.8 (6-14)
Distal to head of fibula to ankle	50 (SD 3.5) m/sec	8.8 (6-14)

Lower Limits of Normal Values  
Peroneal Motor

NCV	40 m/sec	
M-wave amplitude		2.5

d. Sensory Studies

Sensory nerve studies involve recording the response from the nerve-the evoked sensory action potential (ESAP)-at an appropriate distance from the point of stimulation. In sensory measurements, sensory nerve action potentials are recorded that are of much lower amplitude than the evoked muscle action potentials recorded in motor studies. A supramaximal stimulus is used, but the threshold stimulus and the supramaximal stimulus are closer in voltage. Care must be taken to avoid contamination of the sensory recording by muscle action potential "artifact", especially when using antidromic stimulation techniques.

(1) Median Sensory (Antidromic)

(a) Procedure--DISTAL

- (i) Position the active ring electrode on the index finger, 1.0 cm distal to the interdigital cleft.
- (ii) Position the reference electrode on the same index finger 2.0 cm distal to the active lead.
- (iii) Place the ground between the active electrode and the point of stimulation. (Ground may remain unchanged.)
- (iv) When stimulating at the wrist, position the stimulating cathode over the median nerve 2.0 cm proximal to the distal wrist crease. For best results, the electrodes should be positioned between the P. longus and F. carpi radialis tendons, (between two tendons on midline of wrist). There should be a minimal separation of 2.0 cm between the anode and cathode and the anode should be 2.0 cm further proximal than the cathode.
- (v) When stimulating at the elbow, position the stimulating cathode over the median nerve at the level of the elbow crease, (just below bicep definition).
- (vi) Stimulus duration should be 0.1 or 0.2 msec.
- (vii) Stimulus intensity should be adjusted to produce a brief twitch of the abductor pollicis muscle. This should be super-maximal for the compound sensory negativity. (Intensity remains unchanged.)
- (viii) Stimulus rate should be 1 per sec.
- (ix) Switch Volts/Div. to 10 uV
- (x) Change Filter to "SCV"
- (xi) Stimulate and measure onset latency, record.

(b) Procedure--PROXIMAL

- (i) Intensity remains unchanged.
- (ii) All settings remain unchanged.
- (iii) Stimulate and measure onset latency.
- (iv) Measure distance between stimulating sites (mm).

- (v) Measure distal stimulator site to active electrode.
- (vi) The normal range for sensory latencies is approximately 2 to 3.5 msec.

(vii) Normal Values (Sensory; Antidromic)

<u>Amplitude</u>	<u>Sensory Latency or NCV</u>
Equal or slightly higher than orthodromic	3.2 ± 0.25 msec

Lower Limits of Normal Values

Median Sensory	
NCV (proximal)	50 m/sec
NCV (distal)	45 m/sec
Peak Amplitude	6.0 uV

(2) Ulnar Sensory (Antidromic)

(a) Anatomy

The ulnar nerve is the motor nerve to the muscles of the ulnar side of the forearm and hand and the sensory nerve to the skin of the ulnar aspect of hand, the fifth digit, and the ulnar half of the fourth digit. It receives contributions from C8 and T1, which pass through the lower trunk and medial cord of the brachial plexus to occupy a superficial position along the medial side of the arm and forearm as the ulnar nerve.

(b) Applications

The ulnar nerve may be involved in compressive lesions in the hand, wrist, elbow, and thoracic outlet. The lower trunk and medial cord of the brachial plexus are in close proximity to the first rib.

(c) Procedure

- (i) Position the active ring electrode surrounding the 4th and 5th digits, 1.0 cm distal to the interdigital cleft. (on little finger)
- (ii) Position the reference electrode 2.0 cm further distally on the same finger. Place the ground on the palm of the hand. (May remain unchanged.)
- (iii) Position the stimulating cathode over the flexor carpi ulnaris tendon, about 14.0 cm further proximal to the active recording site. (Medial side of forearm.)

- (iv) Stimulus duration should be 0.1 or 0.2 msec.
- (v) Stimulus intensity should be adjusted to elicit a supramaximal initial negative component in the compound action potential.
- (vi) Stimulus rate should be 1 per sec.
- (vii) Note - Sural nerve response may not be evident in approximately 15% of normal individuals.
- (ix) Volts/Div. to 10
- (x) Stimulate and measure onset latency.
- (xi) Measure amplitude.
- (xii) Measure distance between distal stimulation site and active electrode.
- (xiii) Normal Values (Sensory; Antidromic)

<u>Amplitude</u>	<u>Sensory Latency (or NCV)</u>
Same or slightly higher than orthodromic	3.2 ± 0.3 msec

Lower Limits of Normal Values

Ulnar Sensory	
NCV	50 m/sec
Peak Amplitude	7.0 uV

(3) Sural Sensory (Antidromic)

(a) Anatomy

Sural sensory fibers originate from the S1 root segment, traverse the sacral plexus, and course distally to the sciatic nerve. The sural nerve proper is formed by the union of the medial sural cutaneous branch and the peroneal nerve. The sural nerve becomes superficial at approximately midcalf after which it runs behind the malleolus and becomes the lateral dorsal cutaneous nerve over the dorsum of the foot. In participants with an accessory deep peroneal nerve, it may be necessary to perform testing of the sural nerve orthodromically because of the large muscle potential from the extensor digitorum brevis that results after stimulation in the midcalf.

(b) Applications

Study of the sural nerve is useful in distinguishing S1 and S2 radiculopathies from lesions involving and distal to the S1 dorsal root ganglion. The sural nerve often develops abnormal responses--especially amplitude decrement--early in the course of polyneuropathies. It may be impossible to evoke an action potential from the sural nerve in persons more than sixty years old.

(c) Procedure

- (i) Place the active electrode over the sural nerve at the level of the lower tip of the lateral malleolus. (Just below and behind ankle bone.)
- (ii) Place the reference on the lateral surface of the same foot at the base of the fifth digit.
- (iii) Position the ground on the lower calf, between the stimulating and recording electrodes.
- (iv) Position the stimulating cathode approximately 14.0 cm proximal to the active electrode along the dorsal mid-calf.
- (v) Filter to "SCV".
- (vi) Stimulus duration should be 0.2 msec.
- (vii) Volts/Div. to 10  $\mu$ V.
- (viii) Stimulus intensity should be supra-maximal for the sensory negativity. (No muscle contraction should be visible - Should be felt on lateral aspect of foot.)
- (ix) Stimulus rate should be 1 per sec.
- (x) Measure onset latency and amplitude.
- (xi) Measure from distal stimulation site to active electrode.
- (xii) Normal Values

Age (years)	Sensory latency (or NCV)	Amplitude (uV)
15	<4.2 (mean 3.6)	>5 (mean 15)
65	<4.6 (mean 3.9) msec	>3 (mean 8)

Lower Limits of Normal Values

Sural Sensory		
NCV	45 m/sec	
Peak Amplitude		4.0 uV

(xiii) Calculate conduction velocities and enter into computer terminal.

(xiv) Formula for calculating conduction velocities:

Motor: Calculate the NCV over the various segments of the motor nerves. First calculate the conduction time between the two stimulation sites:

Conduction time (msec) between stimulation sites = latency (msec) from the proximal stimulation site - latency (msec) from the distal stimulation site.

The NCV can then be calculated:

$$\text{NCV (m/sec)} = \frac{\text{distance between two stimulation sites (mm)}}{\text{conduction time (msec) between two stimulation sites}}$$

NOTE: milliseconds = seconds/1000 and millimeters = meters/1000.

Calculate the NCV.

In a majority of EMG laboratories the sensory NCV is estimated by dividing the conduction distance (millimeters) by the latency (milliseconds).

$$\text{NCV (m/sec)} = \frac{\text{distance between the active stimulating and recording electrodes (mm)}}{\text{latency over the same segment (msec)}}$$

$$\text{Distal velocity in the median sensory nerve (m/sec)} = \frac{\text{distance}}{\text{absolute latency}}$$

## 7. Data Management

As the test is performed, the technician will enter the results onto the data collection form. The final test results, in m/sec,

will be calculated by the technician from previously entered results, as described above. At the conclusion of the entry process, the completed form will be reviewed by the technician for errors and subsequently will become a part of the hardcopy medical record.

a. General Data Flow

- (1) At the beginning of the day, the day's scheduling report will be distributed to the staff. This report will list each participant that is to have a Nerve Conduction Velocity (NCV) exam for the day. The report does not list the participants in the order to be examined, however it does show the schedule number (1-23) that the participants have been assigned.
- (2) The scheduled participant will arrive.
- (3) The technician will check off the participant on the daily schedule. This will provide an ongoing record of participants that have or have not been examined.
- (4) The technician will perform the NCV examination, noting abnormalities on the exam worksheet. This worksheet is simply a sheet of paper with the major categories of the exam listed on it.
- (5) After the examination is complete, the technician will enter the medical record number assigned to the participant, the name of the participant, the date, the technician's ID #, the exam start time and the exam status.
- (6) The technician will review the results. If errors are found, the technician will go to the incorrect answer and correct it. Once the technician is satisfied with the accuracy of the exam, he/she will verify the narrative by signing it.
- (7) The technician may have comments or impressions regarding the examination that he/she wishes to highlight. In these cases, the technician will handwrite on the bottom of the final narrative any such remarks. If a result is out of range a second technician will verify and initial form.
- (8) The technician will take the data collection form to the nursing station and place it in the appropriate exam slot.

8. Quality Control

The Clinic Manager will be responsible for administrative coordination of the quality control program, under the supervision of the Special Assistant for Quality Assurance and Scientific Affairs. The nerve conduction velocity exam will not be

duplicated in deference to participant convenience, but the Clinic Manager will observe each technician for one entire QPS and nerve conduction velocity test per week. Documentation of the observations will be made on a special quality assurance observation form, one copy of which will be included in the participant's medical record, a second copy of which will be kept in a locked file cabinet in the office of the Special Assistant for Quality Control and Scientific Affairs. In addition, 10% of each week's data from these exams will be sent to Dr. Joseph Arezzo, Albert Einstein University, New York, NY, for his review. Dr. Arezzo will periodically visit the study site to observe technician performance, check machine calibration, and review an additional 10% of the data.

#### 9. Backup

- a. Backup for the TECA TD10 MK1 will be provided by a third machine on site in the clinic area, along with an additional preamp purchased for backup.
- b. Procedure for handling equipment problems: A service contract will be negotiated after the first year of warranty is up for all three machines. A service representative in the Houston, Texas, area is within an hour's flight time, and in the worst case, would be in Albuquerque within one week of receiving a call.
- c. Backup technicians will be provided from a pool of electrodiagnostic technicians who are cross-trained for NCV, QPS and Audio and Visual testing.

#### 10. Subject Problems

If, during the course of testing, a participant decides to terminate or refuses the NCV test, the Clinic Manager will be notified. The participant then will be reminded of the importance of completing the test, recognizing that the individual has the right to refuse. If the participant still at that time decides not to continue the test, a refusal with signature of participant and Clinic Manager will be entered into his record.

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