

PERIPHERAL NEUROPATHY: VIBRATION PERCEPTION THRESHOLD**TABLE OF CONTENTS**

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PERIPHERAL NEUROPATHY: VIBRATION PERCEPTION THRESHOLD

1. Peripheral neuropathy background and rationale

Decrements in peripheral nerve function are known to increase both with advancing age and in the presence of diabetes mellitus. Since peripheral neuropathy (PN) involves both sensory and motor functions, PN may be associated with decrements in balance, strength, and mobility, all disability-related outcomes that are central to the scientific objectives of Health ABC.

Supporting a potential association between PN and various aspects of physical function in old age are several small studies in older adults that have suggested these effects. PN may be related both to performance tests and strength measures in the lower extremity, and are of equal scientific importance in older individuals with and without diabetes. Measures of PN in Health ABC include standard tests that have been used in other epidemiologic studies, and involve measurement of both sensory and motor nerve function. PN measurements are divided into three parts:

- Quantitative sensory testing (QST) of the great toe using the Medoc vibration device,
- Nerve conduction (NC) studies using the NeuroMax 1002 to measure several parameters associated with the peroneal nerve, and
- Testing of loss of protective sensation using the monofilament.

QUANTITATIVE SENSORY TESTING

General description of vibration threshold testing with the Medoc VSA-3000

Quantitative sensory testing (QST) is the use of precisely measured and repeatable sensory stimuli to determine the absolute threshold of sensation within specific somatosensory modalities. When properly performed, QST can increase the sensitivity and reliability of the clinical assessment of sensory function. The principal strengths of QST include simplicity, permitting testing by non-professional personnel, and the availability of mean and standard deviation values that are accurate and age-controlled. QST is especially recommended for rapid screening of large populations and/or for the longitudinal evaluation of participants. QST is a non-invasive, pain-free technique.

For QST in Health ABC, vibration perception threshold will be measured using the *method of limits*. In this quick method, the seated participant places the plantar surface of the right great toe on a small vibrating surface located on the measurement device. The vibration intensity increases from a defined starting point, until the participant ‘stops’ the stimulus by pushing a button on a hand-held indicator (‘clicker’) as soon as they perceive the vibration. The vibration is created by an electromagnet at a rate of 100Hz, and the vibration increases by precise computer control of the voltage. The computer presents vibration amplitude in microns, the standard unit for this measurement. These values are calculated by the computer, based on a predetermined voltage-amplitude calibration table.

The method of limits is “time inclusive,” since it includes participant's reaction time. The rate at which the vibration increases is set at 0.8 microns per second in order to reduce measurement

error resulting from differential rates of increase. To administer the protocol, the participant needs to have their sock removed from the leg being tested, and the pant leg rolled up to the calf. The foot should be warmed to at least 30°C. Several trials are performed, and the mean of the peak values is taken as the threshold. The Health ABC protocol includes five trials to limit measurement variability.

The Medoc VSA-3000 Vibratory Sensory Analyzer is the device that will be used to measure vibration perception threshold in Health ABC. The Medoc is a portable device composed of a foot & hand support stimulator, a power supply, a hand-held 'clicker,' and Windows-based operating software. Data are stored in the computer, and will be exported to an IBM-compatible computer. The Medoc has numerous settings for vibration threshold studies. For Health ABC, the device will be set to use the "Method of Limits." The vibrating white button on the Medoc is designed in order to provide a standard 50 g force against the plantar aspect of the great toe, limiting measurement variability due to participant's foot pressure on the white button.

2. Equipment and supplies

- Surface thermistor
- Medoc VSA-3000 Vibratory Sensory Analyzer
- Heating pad
- Laptop or desktop hook-up for data storage
- Alcohol wipes
- Lab towels ("plasback" or plain)
- Paper foot pads (Sahara exam paper)
- Bean bag
- Examination gloves
- Sani Wipes

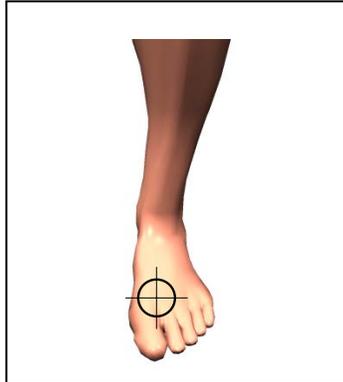
3. Safety issues and exclusions

Participants are excluded if they are missing both great toes (e.g., both great toes have been amputated).

4. Participant preparation

The surface of the Medoc should be thoroughly cleaned with Sani Wipes between participants. Testing is done on bare skin on the center of the bottom of the great toe on the right foot, unless the left toe was tested in the prior visit or the right toe is contraindicated. Have the participant remove socks, stockings, etc., and roll up pant leg to mid calf. Contraindications for testing on the right toe include amputation, ulcer, trauma, and surgery. If a contraindication is present, test on the left toe, and record on the data collection form why the right toe was not tested.

Prior to testing, measure the surface temperature of the dorsum of the foot with the surface thermistor (see figure below). The thermistor should be held approximately 4 inches from the foot.



Skin temperature should be at least 30°C. If the foot is below this temperature, use the heating pad (set at 107° F or 41.7°C) to warm the foot until it reaches 30°C, and record the second measurement on the data collection form. If you are unable to warm the foot adequately after 5 minutes, record the surface temperature on the data form and perform the test. Leave the fields for the second temperature measurement (called “Foot temperature following heating”) blank if the participant’s initial foot temperature was at least 30°C.

Prior to testing, participants should be given an opportunity to become familiar with the testing apparatus and with the expected vibratory sensations. During this period, the examiner can instruct the participant as to the way in which to place the foot on the vibrating white button. Participants need to sit upright with their lower leg at a right angle to their upper leg. This position will ensure that their toe drops onto the white button. If the participant is leaning back or does not have their lower leg at a right angle to their upper leg, their toe will come up and may not be in contact with the white button. In addition to familiarizing the participant with the equipment and testing procedure, the adaptation period will also allow the examiner to determine the Start Level, using the “Manual” protocol.

5. Detailed measurement procedures

The clinic visit interview includes a series of questions about leg cramps and neurologic symptoms. These questions will have been asked before the peripheral neuropathy tests.

Start QST Hardware

Click on WinTSA icon.

Wait for initialization.

After initialization, pick Vibratory Stimulator mode on the left of the screen at the bottom.

Click “Test (perform a test).”

Click “ADD” (for a new participant).

Enter only the acrostic, ID#, year of birth, gender and examiner ID#.

Click “OK.”

Click “Continue” twice until you reach “Program type” screen which includes “Levels,” “Limits,” and “Manual.”

Highlight “Manual” and click “Continue.”

Look at settings for the “Manual” test. Confirm that settings are as follows:

“Start” = “0.”
“Rate” = “5.”
“Destination” = “130.”

Begin preparing the participant for the test.

Script: “I need to make sure that your foot is warm enough to do this next test. I’m going to measure the temperature of your foot before we start.”

Refer to the Data from Prior Visits Report to see which foot to test. Measure the participant’s skin temperature on the dorsum (top) of the foot being tested using the surface thermistor. If the foot listed on the Data from Prior Visits Report cannot be tested because of ulcer, trauma, surgery, or amputation, record the temperature of the other foot. If the participant did not have this test at Year 4, perform the test on the right foot unless contraindicated.

Record initial temperature on the data collection form.

Attempt to warm the foot to at least 30 degrees centigrade if the initial temperature is below that level.

Place the stimulating white button on a table so the participant can touch the vibrating white button with their hand.

Script: “Now we will do a practice test so you can see what this test feels like. Most people say it feels like a vibration or buzzing sensation.”

Place the participant’s hand on the white button and allow them to feel the vibration.

Record the foot temperature on the data collection form after heating.

Have the participant clean their big toe with an alcohol pad. Some participants may need assistance cleaning their toe. Place the paper foot guard on the platform, ***being careful not to cover the vibrating white button.***

Describe the test to the participant, and allow them to become familiar with the equipment.

Script: “This test measures your ability to feel very small vibrations in your feet. To do this, I’m going to ask you to place your foot on this machine, with your big toe on the white button that will vibrate (*point to surface*). It won’t hurt at all. Let’s start by getting used to how the vibration feels, and how to use the button.

Help the participant place their foot and toe on the device. Place a bean bag over the top of the foot to ensure consistent contact with the vibrating white button.

Script: “This white button will vibrate. Place your big toe on the foam over the button so it is flat with the surface of the platform. You don’t need to press your toe down at all. Just lay your toe flat over the button.

“Now we will do a practice test. When you feel the vibration, press the computer mouse button. Just try to pay attention to your toe, and press the button when you feel the vibration. (*Show the mouse and indicate how to push the button. Have the participant rest their finger on the button.*) It may take some time, so don’t become discouraged. Please don’t guess.”

The participant should be seated so they cannot see the computer screen.

Script: “Please close your eyes. I am beginning the practice test.”

To initiate the pre-test, click the “Start” button.

When the participant feels the vibration, have them press the button on the computer mouse to “stop immediately.” The screen will have an “amplitude” in the upper right corner marked “stopped at: . . .” Repeat the pre-test two more times. Choose the lowest of the three values obtained during these practice tests and record this number on the data collection form. Subtract 20 from this number, then round down to the nearest multiple of 10. This will be the participant’s baseline starting point on the vibration perception threshold test, the Method of Limits. (Example: The participant says they feel it, you hit the stop button on the laptop, the “amplitude” is 32.6. Subtract 20, which is 12.6, and round down to the nearest multiple of 10 which is 10.) This is the “baseline” for the actual vibration test. Record this number on the data collection form in the field labeled “Baseline value for the test.”

Note: If the “stop” number on the computer screen is less than 20, the baseline value for the test is “0.” If the “stop” number on the computer screen is either 120 or 130 (maximum value), the baseline value is “90.”

Click “exit” (the “Manual” test).

The pre-test is now complete.

Begin the test using the Method of Limits.

Highlight the "Limits" test on the left, and highlight "Limits – 2" on the right. This is the protocol for the foot, and click "Continue."

Pick the foot on the body figure on the left, then pick the exact part, the foot in the text fields on the right: It should be "Toe/big"

Click "Continue." You should now be on a yellow screen. Choose "Edit." Highlight "Starting level (micron)" and type in the start level from the pre-test. Click "OK."

Script: "Now we'll begin the next test. The vibration will start very softly and get stronger. As soon as you feel the vibration, push the button to indicate that you have felt the vibration. (*Show the mouse and indicate how to push the button. Have the participant rest their finger on the button.*) We will do this several times in a row. After you press the button, there will be a delay before the next vibration starts. Each time you feel the vibration, just press the button right away to indicate that you have felt the vibration. The vibration will stop immediately. Over the next few minutes, you may feel the vibration several times. Just try to pay attention to your toe, and each time you feel the vibration, push the button. Remember that we want to know when you first begin to feel it. If you don't feel it we don't want you to guess. Again, please close your eyes before we begin the test. Ready?"

Administer the test by clicking "Run." If you need to pause during the test, you can press "S". When the last stimulation is felt, the examiner should record "Avg" and "Var" from the screen (upper left corner) on the data collection form. If the variance is >750 microns, then do not save the trials and re-start the test from the beginning. After the last stimulation, hit SAVE!

Note: If the participant does not feel the maximum stimulation (130 microns) after two trials, you may stop the test. Indicate on the data collection form that two trials were completed and that the participant was unable to feel the vibration. Go to the peroneal motor nerve conduction test.

After the test is completed, measure the participant's post-test skin temperature on the dorsum of the foot, again holding the thermistor approximately 4 inches from the surface of the foot.

Record the foot temperature on the data collection form.

Record whether five trials were completed, and if not whether one, two, three, or four trials were completed (Question #9 of the Vibration Perception Threshold data collection form in the Clinic Visit Workbook).

Record the results from the upper left corner of the computer screen, (AVG value) in microns, onto the data collection form (Question #10), in the field labeled, "Record average result from the computer screen."

Record the variance (VAR value) from the upper left corner of the computer screen onto the data collection form (Question #11) in the field labeled, "Record variance from computer screen." If the variance is 750 microns or greater, re-test. If variance is less than 750 microns, the test is done.

Thank the participant.

If re-testing: Record whether five trials were completed, and if not whether one, two, three, or four trials were completed (Question #13 of the Vibration Perception Threshold data collection form in the Clinic Visit Workbook).

Record the results from the upper left corner of the computer screen, (AVG value) in microns, onto the data collection form (Question #14), in the field labeled, "Record average result from the computer screen."

Record the variance (VAR value) from the upper left corner of the computer screen onto the data collection form (Question #15) in the field labeled, "Record variance from computer screen." If the variance is 750 microns or greater, flag for quality control.

Thank the participant.

6. Procedures for performing the measurements at home (if applicable)

Not applicable.

7. Procedures for exporting vibration files

Field centers back up vibration files each week. As you get ready to create your weekly data backup, you will create a file following the instructions below (Section 7.1).

7.1 Exporting vibration files

- 1) Go to "Menu"
- 2) Go to "Utilities"
- 3) Select "Back up and restore"
- 4) Select "C:" drive
- 5) A backup folder of all participant records will be created in "C:/Medoc/wtsa5_35/Backup.
- 6) Insert a CD
- 7) Click on the backup folder and select send to CD drive.

8. Alert values/Follow-up/Reporting to participants

These test results have no alert values and are not reported to the participant or physician.

In response to questions asking, “**Am I normal?**” or “**How did I do?**,” the following response is suggested:

“Right now there is very little information about how this test relates to the health of older people. Part of why we are doing this test is to help answer that question.”

In response to questions from participants who **don’t feel the vibration at all**, and ask about it, the following response is suggested:

“Everyone senses this test differently, and not everyone feels the vibration. We will be looking at how different responses to the test relate to the health of older adults.”

9. Quality assurance

To address the subjective nature of QST measures, and to ensure that the participant is adhering to the directions, the Medoc includes time lags between trials. During the acclimation period, these lags can be used to assess whether the participant is following the directions (e.g., pressing the hand-held indicator during periods of stimulation, rather than randomly during lag times). This can help reduce false measurements. However, it should be emphasized that some Health ABC participants will have high vibration threshold measurements, and this should not be confused with failure to follow directions during the acclimation period or during testing.

The Medoc includes a variance feature that calculates the cumulative variance of the trials between each trial in the method of limits. This feature can be used to help identify specific ‘outlier trials’ within an individual, and to help identify participants whose trial variance falls out of an acceptable range in the study. The field calibration kit should be used regularly to calibrate the device at both sites.

9.1 Training requirements

The examiner requires no special qualifications or experience to perform this assessment. Training should include:

- Read and study manual
- Attend Health ABC training session on measurement techniques
- Practice measurement protocol on other staff or volunteers
- Discuss problems and questions with local expert or QC officer

9.2 Certification requirements

- Complete training requirements

- Conduct exam on four volunteers, two of whom should be re-tested.
(Volunteers need not be age-eligible for Health ABC.)

9.3 Quality assurance checklist

- Main points of script correctly and clearly delivered
- Correctly warms foot, if necessary, before administration of protocol
- Correctly positions the participant and the foot
- Correctly describes testing procedure
- Correctly demonstrates use of the mouse
- Conducts acclimation period / practice tests correctly
- Correctly collects four threshold measurements using the method of limits
- Correctly records whether or not variance from computer screen is greater than 750 microns
- If necessary, retests
- Correctly stores data in computer for subsequent downloading
- Reviews form for completeness following completion of test
- Acceptable test-retest results

10. Data collection form

	HABC Enrollment ID #	Acrostic	Type of Annual Contact	Staff ID#
	<input type="text" value="H"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input checked="" type="radio"/> Year 11 <input type="radio"/> Other1 <input type="radio"/> Other2	<input type="text"/> <input type="text"/> <input type="text"/>

VIBRATION PERCEPTION THRESHOLD ★

- Record surface temperature of the dorsum (top) of the right foot (unless instructed otherwise) using the surface thermistor. Warm the foot to at least 30°C if initial surface temperature is below that level. If the right foot cannot be tested because of ulcer, trauma, surgery, amputation, or Data from Prior Visits Report instructions, record the temperature of the left foot. (Examiner Note: Test foot noted on Data from Prior Visits Report.)

Script: "I need to make sure that your foot is warm enough to do this next test. I'm going to measure the temperature of your foot before we start."

Measure the participant's skin temperature on the dorsum of the foot.

Initial foot temperature: <input type="text"/> <input type="text"/> . <input type="text"/> °C

- If initial foot temperature is below 30°C, use heating pad to achieve at least 30°C.

Place the stimulating white button on a table so the participant can touch the vibrating white button with their hand.

Script: "Now we will do a practice test so you can see what this test feels like. Most people say it feels like a vibration or buzzing sensation."

Place the participant's hand on the white button and allow them to feel the vibration.

Record foot temperature following heating and proceed with testing. If, after 5 minutes of warming, foot temperature does not reach 30°C, record temperature below and proceed with testing.

Foot temperature following heating: <input type="text"/> <input type="text"/> . <input type="text"/> °C	Leave blank if participant's initial foot temperature was at least 30°C.
---	--



HABC Enrollment ID #	Acrostic	Type of Annual Contact
H		<input checked="" type="radio"/> Year 11 <input type="radio"/> Other1 <input type="radio"/> Other2

VIBRATION PERCEPTION THRESHOLD

3. ***Have the participant clean their big toe with an alcohol pad. Place the paper foot guard on the platform, being careful not to cover the vibrating white button. Describe the test to the participant, and allow them to become familiar with the equipment.***

Script: "This test measures your ability to feel very small vibrations in your feet. To do this, I'm going to ask you to place your foot on this machine, with your big toe on the white button that will vibrate (point to surface). It won't hurt at all. Let's start by getting used to how the vibration feels, and how to use the button."

Help the participant place their foot and toe on the device. Place a bean bag over the top of the foot to ensure consistent contact with the vibrating white button.

Script: "This white button will vibrate. Place your big toe on the foam around the button so it is flat with the surface of the platform. You don't need to press your toe down at all. Just lay your toe flat over the button."

"Now we will do a practice test. When you feel the vibration, press the computer mouse button. Just try to pay attention to your toe and press the button when you feel the vibration."

Show the mouse and indicate how to push the button. Have the participant rest their finger on the button.

Script: "It may take some time, so don't become discouraged. Please don't guess."

The participant should be seated so they cannot see the computer screen.

Script: "Please close your eyes. I am beginning the practice test."

To initiate the pre-test, click the "Start" button.

When the participant feels the vibration, have them press the button on the computer mouse to "stop immediately." The screen will have an "amplitude" in the upper right corner marked "stopped at: . . ." Repeat the pre-test two more times. Choose the lowest of the three values obtained during these practice tests and record this number on the data collection form. Subtract 20 from this number, then round down to the nearest multiple of 10. This will be the participant's baseline starting point on the vibration perception threshold test, the Method of Limits.



HABC Enrollment ID #	Acrostic	Type of Annual Contact
H [] [] [] [] [] []	[] [] [] [] [] []	<input checked="" type="radio"/> Year 11 <input type="radio"/> Other1 <input type="radio"/> Other2

VIBRATION PERCEPTION THRESHOLD ★

4. "Stop" number on the computer screen:

[] [] [] . [] [] microns

Subtract 20.0 microns

5. "Stop" number minus 20:

[] [] [] . [] [] microns

Round this number down to the nearest multiple of 10.

6. Baseline value for the test:

[] [] [] microns
(0, 10, 20, 30, 40, etc.)

(Examiner Note: If the number is less than "20," go to Question #6 below and record "0" for the Baseline value. If the number is 120 or 130 [maximum value] go to Question #6 below and record "90" for the Baseline value.)

Script: "Now we'll begin the next test. The vibration will start very softly and get stronger. As soon as you feel the vibration, push the button to indicate that you have felt the vibration. **(Show the mouse, rest finger on the mouse button, and indicate how to push the button.)** We will do this several times in a row. After you press the button, there will be a delay before the next vibration starts. Each time you feel the vibration, just press the button right away to indicate that you have felt the vibration. The vibration will stop immediately. Over the next few minutes, you may feel the vibration several times. Just try to pay attention to your toe, and each time you feel the vibration, push the button. Remember that we want to know when you first begin to feel it. If you don't feel it we don't want you to guess. Again, please close your eyes before we begin the test. Ready?"

Administer the test.

7. Which great toe was tested?

Right

Left

Neither

Why wasn't the right toe tested?
(Examiner Note: Mark all that apply.)

Left toe tested at Year 4
 Amputation
 Ulcer
 Trauma or surgery
 Other **(Please specify:**

 _____)

Why wasn't the test done?
(Examiner Note: Mark all that apply.)

Participant refused
 Participant physically unable to cooperate
 Participant unable to follow directions
 Amputation of both great toes
 Other **(Please specify:**

 _____)

Go to Peroneal Motor Nerve Conduction Test.





HABC Enrollment ID #	Acrostic	Type of Annual Contact
H [] [] [] [] []	[] [] [] [] []	<input checked="" type="radio"/> Year 11 <input type="radio"/> Other1 <input type="radio"/> Other2

VIBRATION PERCEPTION THRESHOLD ★

8. Record the post-test surface temperature of the great toe using the surface thermistor.

Foot temperature after test: [] [] . [] °C

9. Were five trials completed? Yes No

How many trials were completed?
 One Two Three Four

Was the participant unable to feel the maximum stimulation (130 microns) at both trials?
 Yes No

Go to Peroneal Motor Nerve Conduction Test.

10. Record average result from computer screen: [] [] [] . [] [] microns

11. Record variance from computer screen: [] [] [] [] . [] [] microns

12. Is variance from computer screen greater than 750 microns?

(Examiner Note: See Question #11 above.)

Yes No

Re-administer Vibration Threshold Test. Go to Question #13. No

Go to Peroneal Motor Nerve Conduction Test.

13. Were five trials completed? Yes No

How many trials were completed?
 One Two Three Four

Was the participant unable to feel the maximum stimulation (130 microns) at both trials?
 Yes No

Go to Peroneal Motor Nerve Conduction Test.

14. Record average result from computer screen: [] [] [] . [] [] microns

15. Record variance from computer screen: [] [] [] [] . [] [] microns

If over 750 microns, flag for quality control.

