



## INSTRUCTIONS FOR THE PERIPHERAL NEUROPATHY (PNF) FORM (v 1.0)

### I. General Instructions

The Neuropathy Form (PNF) should be completed by all participants. This form should be completed during the participant's clinic or home visit. Technicians completing this form should be certified and have a working knowledge of the relevant Manual of Operations.

Peripheral neuropathy is characterized by numbness, reduction or loss of temperature and pain sensation, tingling, and muscle weakness and atrophy in the lower extremity. Peripheral neuropathy is a common complication of diabetes but could also be due to other conditions. Reduced sensation can lead to a number of complications such as foot ulcers, undetected minor trauma—which can lead to more major complications, and even amputation.

Monofilament testing is a simple, noninvasive test to identify people who have lost protective sensation. The test involves using a nylon monofilament to evaluate touch-pressure cutaneous sensation in the feet. It is commonly used in the clinic as a screening test for peripheral neuropathy.

The monofilament test results will be reported to participants (or their doctor with permission) if the participant has at least one insensate site on either foot. If lesions or ulcers are found in a visual inspection of the feet, these will also be reported back to the participants. These results will be included in the Results Report

**Each monofilament should be used for no more than four (4) participants per day.**

**Detailed Instructions for Each Item**

**A. Preliminary Questions:**

- Using the diagram inspect the right foot and record if there are any amputations on the right foot. If there are no amputations enter 0 for none.

	<ol style="list-style-type: none"> <li>Entire foot</li> <li>Partial foot</li> <li>Partial foot</li> <li>Partial foot</li> <li>Great toe</li> <li>Other toe(s)</li> <li>Other toe(s)</li> <li>Other toe(s)</li> <li>Great toe and other toe(s)</li> <li>Great toe and other toe(s)</li> </ol>
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- Same as in item one but inspect the left foot
- Evaluate both feet for lesions. Lesions are defined as bandages, blisters, ulcers, abrasions, lacerations, and sutures. Fissures between the toes will not be defined as lesions. Bandages or elastic or pressure stockings covering all or part of the foot will not be removed for this assessment even if the participant wants to remove them. The pictures below are examples of types of lesions that may be seen of the foot. For each foot, note if there are any lesions present, and record B, any lesions on both feet, R, right foot only, L, left foot only, or N, none.



4. The procedures for monofilament testing must be explained and demonstrated to the participant. If it becomes clear that the participant cannot follow the instructions for any reason, the monofilament testing should be skipped. Enter Y if the participant fully understands the instructions for monofilament testing. If they do not then enter N, skip to the end of the form.

### **Standard Procedures for conducting the Monofilament Test**

- The participant will be in the supine position, resting quietly. If they cannot lie supine, sitting is allowed as the participant will be asked to close his/her eyes.
- The examiner should wear latex gloves.
- Use the 0.5/10 gram filament to test sensation.
- Starting with the left foot, follow perform the test in the following order; Third Metatarsal Head, Fifth Metatarsal Head, First Metatarsal Head, Hallux
- Check the form for the interval (A or B) in which to apply the stimulus.
- Ask the participant to close his/her eyes.
- Test the first site:
  - When applying the filament, say out loud “A, B.”
  - Do not change the inflection in your voice with the interval change.
  - Apply the filament to the skin’s surface at either Interval A or Interval B as indicated on the form.
  - Apply the filament perpendicular to the skin’s surface.
  - The approach, skin contact, and departure of the filament should be approximately 1.5 seconds duration.
  - The participant can choose one of three options:
    - Interval A
    - Interval B
    - Unknown (U): Unable to determine the interval in which the stimulus was applied (participant could say: “I don’t know”, “I’m not sure”, or “Could you repeat the test” or a similar comment)
    - Other (O) Callus/Scar/Necrotic Tissue/Bandage/Amputation
    - Technician error (T)
- Each site will be tested three (3) times.
- If there is a callus, scar, or necrotic tissue at a site, do not perform the test and record “Other” for all tests at that site. You should examine the planter surface of the foot with your hands for the presence of calluses when assessing the foot for abnormalities. Calluses are not always visible to the eye and you want to confirm that the site to be tested for peripheral neuropathy is free of calluses. Although calluses are not recorded as a data point for ARIC, the presence of very large and thick calluses may interfere with peripheral neuropathy testing. If a callus is present, the technician should lightly touch the plantar surface of the foot in the metatarsal area to determine the thickness and spread of the callus. If the callus covers the entire metatarsal area, or the entire top half of the foot, monofilament testing cannot be done on that site so record “Other” for that site.
- Repeat on the right foot.
- After the exam is completed, clean the monofilament with alcohol wipe replace in the case.

The following script and demonstration should be read and performed by the technician.

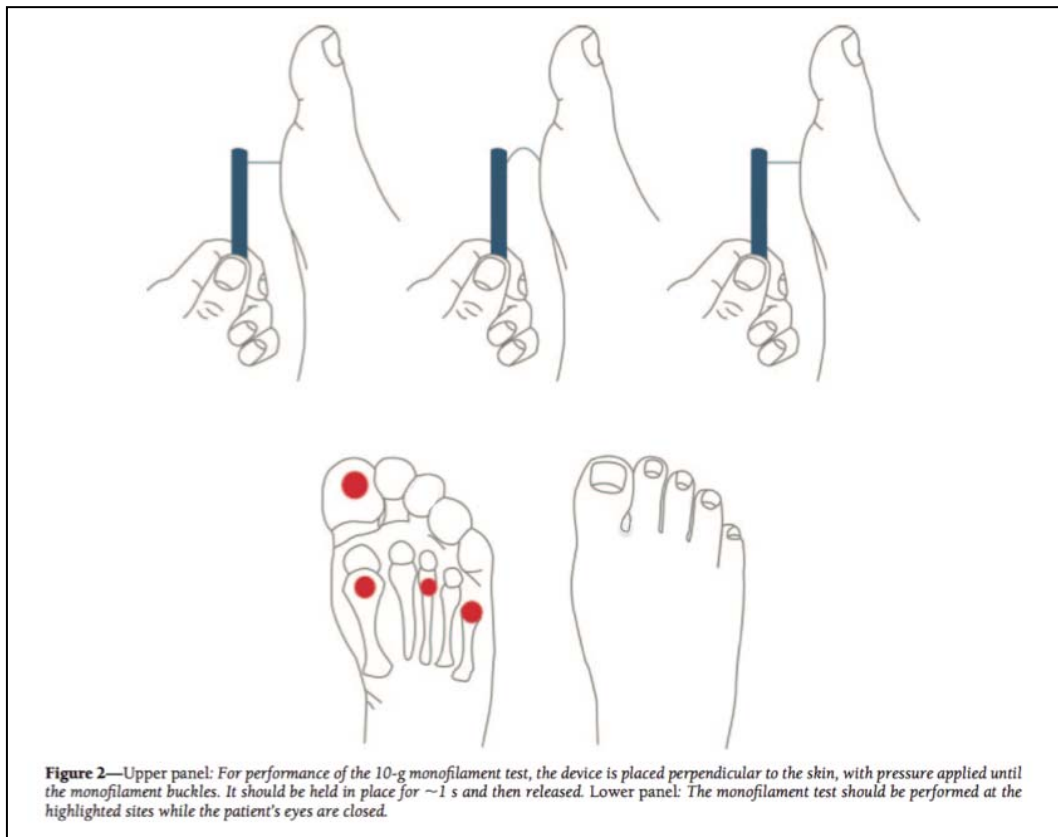
**Script:** “I want to test the sensation or sense of touch on the bottom of your feet. To do this test, I will use this small filament to touch different spots on your foot. It is not sharp and will not break the skin. Let me show you on your hand.”

*(Technician will show the participant the filament and touch the participant’s index finger with the filament so the participant will know what to expect.)*

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

*(Take the participant’s hand).*

“Now close your eyes.” *(Apply the monofilament to the index finger during interval B, and if the participant does not immediately respond “A” or “B,” ask the participant “When did you feel the filament, when I said ‘A’ or when I said ‘B’?” Be sure the participant understands the test before starting. Repeat the explanation and demonstration if necessary.)* The participant should not be able to see which part of the foot is being tested.



For items 5-11b:

- For each site on each foot the letter in bold is the letter you will use to touch the foot. For example, for item “5a. Test 1 **A**: results”, the letter **A** is bolded so you will touch the foot when you say the letter **A**, see below on the item by item.
- If the participant responds with the letter “A” then choose “A”.
- If they respond with “B” then choose “B”.
- If they have a callus, scar, necrotic tissue, amputation, bandage then select “O” for other.
- It is possible that the participant may not have understood the explanation or has lost concentration briefly during the exam and may say ‘I don’t know,’ ‘I’m not sure,’ ‘Could you repeat the test?’. In these situations, the technician should enter the first response given for that site, all of these responses would be coded as “U” unknown.
- If the technician inadvertently administered the test incorrectly choose “T” technician error.
- **You should not ever repeat the test for any site.**

#### **Monofilament Testing Left Foot – Third Metatarsal Head**

- 5a. Left Foot, Third Metatarsal Head, First Test: apply the filament when you say the letter “**A**”
- 5b. Left Foot, Third Metatarsal Head, Second Test: apply the filament when you say the letter “**A**”
- 5c. Left Foot, Third Metatarsal Head, Third Test: apply the filament when you say the letter “**B**”

#### **C. Monofilament Testing Left Foot – Fifth Metatarsal Head**

- 6a. Left Foot, Fifth Metatarsal Head, First Test: apply the filament when you say the letter “**A**”
- 6b. Left Foot, Fifth Metatarsal Head, Second Test: apply the filament when you say the letter “**B**”
- 6c. Left Foot, Fifth Metatarsal Head, Third Test: apply the filament when you say the letter “**B**”

#### **D. Monofilament Testing Left Foot –First Metatarsal Head**

- 7a. Left Foot, First Metatarsal Head, First Test: apply the filament when you say the letter “**B**”
- 7b. Left Foot, First Metatarsal Head, Second Test: apply the filament when you say the letter “**A**”
- 7c. Left Foot, First Metatarsal Head, Third Test: apply the filament when you say the letter “**B**”

#### **E. Monofilament Testing Left Foot –Hallux**

- 8a. Left Foot, Hallux, First Test: apply the filament when you say the letter “**B**”
- 8b. Left Foot, Hallux, Second Test: apply the filament when you say the letter “**A**”
- 8c. Left Foot, Hallux, Third Test: apply the filament when you say the letter “**A**”

**F. Monofilament Testing Right Foot –Hallux**

- 9a. Right Foot, Hallux, First Test: apply the filament when you say the letter “A”
- 9b. Right Foot, Hallux, Second Test: apply the filament when you say the letter “B”
- 9c. Right Foot, Hallux, Third Test: apply the filament when you say the letter “A”

**G. Monofilament Testing Right Foot –First Metatarsal Head**

- 10a. Right Foot, First Metatarsal Head, First Test: apply the filament when you say the letter “A”
- 10b. Right Foot, First Metatarsal Head, Second Test: apply the filament when you say the letter “B”
- 10c. Right Foot, First Metatarsal Head, Third Test: apply the filament when you say the letter “B”

**H. Monofilament Testing Right Foot –Third Metatarsal Head**

- 11a. Right Foot, Third Metatarsal Head, First Test: apply the filament when you say the letter “B”
- 11b. Right Foot, Third Metatarsal Head, Second Test: apply the filament when you say the letter “B”
- 11c. Right Foot, Third Metatarsal Head, Third Test: apply the filament when you say the letter “B”

**I. Monofilament Testing Right Foot –Fifth Metatarsal Head**

- 12a. Right Foot, Fifth Metatarsal Head, First Test: apply the filament when you say the letter “A”
- 12b. Right Foot, Fifth Metatarsal Head, Second Test: apply the filament when you say the letter “B”
- 12c. Right Foot, Fifth Metatarsal Head, Third Test: apply the filament when you say the letter “A”

**J. Scores**

- 13. Right Foot Sensory Score will be calculated by CDART once the form has been saved. This value will be used to determine if the participant has normal, or decreased sensation in the right foot. This value will be included in on the V6 End of Visit Results Report
- 14. Left Foot Sensory Score will be calculated by CDART once the form has been saved. This value will be used to determine if the participant has normal, or decreased sensation in the left foot. This value will be included in on the V6 End of Visit Results Report