

Prior to Testing

- Explain procedure and verify patient understanding and agreement.
- Advise patient about purpose of test and inform them that they will feel a series of 6-12 pulses that may feel like a snapping or tingling sensation.

Testing Procedure - Prepare Patient

- Select exam leg and note which side (R/L) will be used for entry into the DPNCheck device.
- Reminder: Do not test leg with open sores, lesions or wounds.
- Position patient in one of four positions.
Help patient get into the preferred side position (fig. 1) on exam table (on hip opposite of exam leg).
Alternative side and prone positions may also be used on the exam table. See fig. 2 and fig.3.

Exam Table Methods



Preferred position – side



Alternative position – side



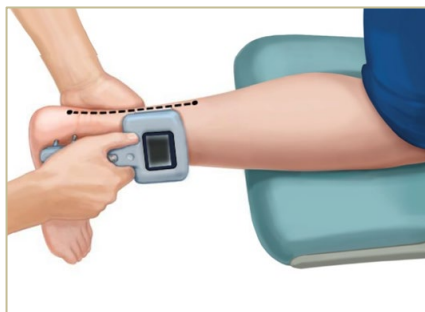
Alternative position - prone

Chair Method



If unable to utilize an exam table:

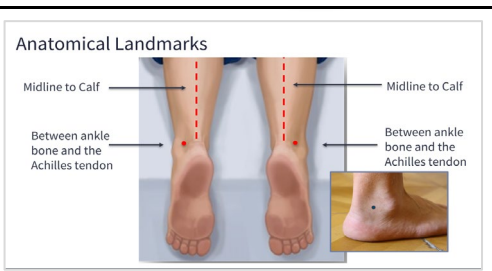
- Use a sturdy chair without wheels, with a padded seat, and preferably with handrails.
- Help patient stand with one leg resting on a chair.
- Instruct patient to bend knee and rest it on seat so leg is supported (see fig. 4).
- Instruct patient to grasp back of chair for stability.



Ensure both the outer ankle bone (lateral malleolus) and Achilles tendon are easily accessible

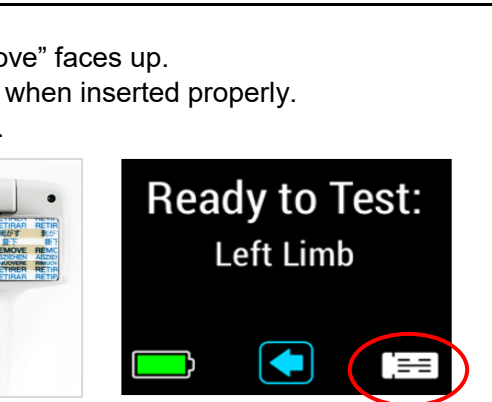
- Scrub (don't just rub) testing area vigorously with alcohol swab and allow testing area to dry.
- Testing area extends from outer ankle near Achilles tendon up the leg 8 inches.




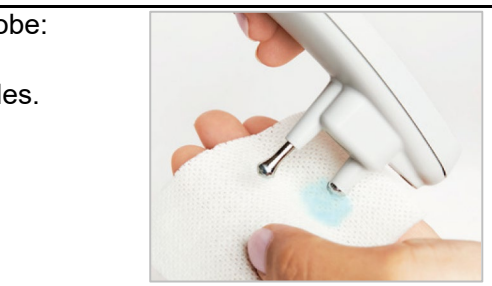
	<p>Establish Landmarks for device placement:</p> <ul style="list-style-type: none"> - Use skin marker if available. - Make sure you have access to the outer ankle bone and the lower calf. - Make sure you can see the midline of the calf. 	 <p>Anatomical Landmarks</p> <p>Midline to Calf</p> <p>Midline to Calf</p> <p>Between ankle bone and the Achilles tendon</p> <p>Between ankle bone and the Achilles tendon</p>
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Testing Procedure - Prepare Device




	<p>Power on the device:</p> <ul style="list-style-type: none"> - Press and release the power button once. - The display will prompt you to connect the biosensor. - If the battery is low, the battery warning will appear on startup. 	
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	<p>Fully insert biosensor into the port:</p> <ul style="list-style-type: none"> - Align biosensor to foam pad and ensure side labeled “Remove” faces up. - Biosensor icon in lower right of the screen will appear white when inserted properly. - Biosensor icon will appear black if it is not inserted properly. 	 <p>Ready to Test: Left Limb</p>
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	<p>Select testing leg (Select Limb = Left/Right).</p>	
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	<p>Apply a small pea-sized amount of conductive gel to each probe:</p> <ul style="list-style-type: none"> - Cover heads of probes in gel. - Use only conductive gel supplied by DPNCheck for electrodes. Do not use ultrasound gel. - Remove any excess gel so it does not smear gel between two probes, which can interfere with results. 	
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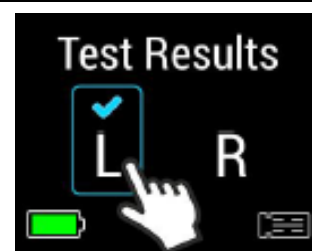
	<p>Remove backing from biosensor.</p>	
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Testing Procedure - Device Placement	
<p>Locate patient's outer ankle bone and align the short probe (anode) and long probe (cathode) to outer ankle bone.</p>	 <p>The long probe should align with the outer ankle bone and placed between the ankle bone and the Achilles tendon.</p> <p>Ensure that device is aligned to the midline.</p> <p>Ensure that blue arrow is pointing to the back of the knee.</p>
<p>Point device with arrows pointed toward back side of knee. Align device with edge of the biosensor placed next to the midline that runs along the Achilles tendon.</p>	
<p>Place the long probe in the soft spot halfway between the center of the outer ankle bone and the Achilles tendon. Tip: The probes should be behind and not over the ankle bone.</p>	
<p>Ensure device is aligned to, but does not cross over the Achilles midline as shown by dashed line in the image above.</p>	
<p>Apply even pressure straight down on device. Check for good contact on both sides of foam pad</p>	
Testing Procedure - Conduct Test	
<p>Press and release button once to start test. The display will show "Testing" and the LED light will blink green when each stimulus is delivered.</p>	
<p>During test, maintain firm and even pressure along device from the probes to the biosensor and maintain steady pressure across entire face of biosensor pad.</p>	
<p>Review test results on the display once completed.</p> <ul style="list-style-type: none"> - The "Amp" value equals the Amplitude. - The "CV" value equals the Conduction Velocity. 	 <p>Normal Response Valid Result</p> <p>Undetectable Response Valid Result</p> <p>Undetectable Response Valid Result</p>
<p>Note: CV may appear with a numerical value for Amplitude, but a "--" for CV - This is a valid result. If Amplitude displays as "0" the CV will also appear as "--" - This is a valid result.</p>	

Testing Procedure - Continued

Retrieve Test Results After Shutoff:

If the test results are no longer shown on the screen or if the device has powered off, they can still be recalled. Disconnect the biosensor to review the last test results, and press on the limb with the blue check mark to bring up results. Ex: The screen pictured indicates that valid test results are available for Left limb. Press the limb with the check mark (e.g., L) to review results for that limb.



Dispose of single patient-use biosensor.

Clean device by wiping probes straight up with alcohol swab or soft cloth. **Do not twist** while cleaning probes.

Troubleshooting/Unsuccessful Test

Key to error messages on display screen. See User Manual if more details are needed.

LED	Error Message	Help Screen
	Biosensor Disconnected	Make sure biosensor tail is inserted then retest.
	Device Locked	Excessive biosensor reuse detected. Device disabled. Call customer service.
	Device Malfunction	Device has malfunctioned. Repeat test. Contact customer service if message persists.
	Excess Gel	Remove probe gel and reapply, make sure that gel does not smear on skin between probes.
	Interference	Check biosensor liner removed, patient leg and foot are relaxed. If message persists, reposition patient.

LED	Error Message	Help Screen
	Limb Not Confirmed	Repeat test with correct limb selected.
	22.5° C Patient Cold	Warm patient's ankle to at least 24C/75F before repeating test. Tester should keep hand away from probes.
	Poor Probe Contact	Reapply probe gel, allowing time for gel to absorb into the skin. Use consistent probe pressure during test.
	Poor Signal Quality	Check biosensor liner removed. Repeat skin preparation, apply consistent pressure to device during test.

LED	Error Message	Help Screen
	Replace Battery	
	Test Error	An error has occurred. Repeat test.
	Upload Error	Check cable fully inserted in both device and PC. Call customer service if message persists.
	Waiting for PC Application	Connect DPNCheck to PC and open Reporter or Communicator.

DPNCheck Reporter - Upload Results (if applicable)

Connect device to PC via USB cable.

Enter Patient ID, data transfers.

Enter required fields: DOB and height.

Enter optional fields if desired: Name, gender, weight.

Select physician and technician if desired.

Enter interpretation and notes if available after physician review.

Select "Complete Study" to finish study.

Generate report and print PDF.

Refer to DPNCheck User Manual for more details if needed.

Results & Patient Follow-Up

Follow your office protocol for provider documentation and review.

Follow your office protocol for patient follow up and education.