DPNCheck®

Program Implementation Guide

CLINIC STAFF/STAND-ALONE CLINIC

DPNCheck 2.0 (Model NC-040)

Let's get started! The DPNCheck® device provides a rapid, objective and accurate test for detecting and staging peripheral neuropathy.

Upon receipt of your DPNCheck device, immediately insert the provided battery into the device and apply the gray foam to the back of the device per the directions on the foam package. A USB cord is also provided within the packaging for PC communication.

Install Battery

- Remove battery door with thumb/finger at arrow
- Insert the CR123A battery, match +/- to indicators

Apply Gray Foam

- Remove brown liner (stickier), align with device.
- Remove white liner and keep for protection of foam when not in use.

Please save the envelope of printed training documents that have been provided within the device package.
Documents include:

- DPNCheck Reference Guide
- Patient Positioning Guide
- Sural Nerve Interpretation Guide

If the materials have been inadvertently discarded, or additional downloadable copies are needed, all resource and educational documents are available in a digital format at the online resource center: www.DPNcheck.com/training

Staff Training Checklist

1

To introduce DPNCheck to the local team has developed an easy to learn library of online videos, appropriate for both clinical and non-clinical staff. Your corporate office has been trained on the device and has appointed a "Program Lead" for each clinic. The Program Lead will support local training activities with your team. Instruct the local team to view the training videos within a specified timeframe and encourage them to collect additional questions or areas that would benefit from further explanation and a live demonstration.

What is covered in the online training video?

- The DPNCheck Value Proposition
- Successful Patient Testing
  - Position
  - Preparation
  - Placement
- Test Result Indicators: *Amplitude and Conduction Velocity*
- DPNCheck Troubleshooting
- Device Maintenance, Cleaning & Reuse
- Online Resources & Partner Support

For staff convenience, the training videos can be viewed based upon the local implementation timeline. A detailed Training slide deck has also been provided as support for additional in-service meetings that will be conducted by the appointed Program Lead. All training videos can be accessed from the DPNCheck Video Training Library website here: www.DPNCheck.com/training/videos

Or directly from the linked titles below:

- Device Training (18 minutes)
- Live Device Patient Demonstration (12 minutes)
- Training Slide Deck (PDF download)

At the end of the two (2) staff training videos, the local team should understand the device and how to conduct a patient test. Staff should have a good basis to advance to Step #2 of training which is live practice.

Typically, Step #1 is successfully completed within the first ten (10) days of receiving the DPNCheck device.

2 The appointed local Program Lead will conduct a live in-service demonstrating the DPNCheck device and a patient test, allowing time for staff Q&A. After which, staff is encouraged to practice on each other. We recommend each site begins with a minimum of one (1) training kit of 25 biosensors per device to ensure that all staff members have several opportunities to practice using the device on different subjects and walking thru the testing protocol. The Program Lead provides real-time coaching to staff to ensure that confidence and competency is instilled in performing an end-to-end patient test.

At the conclusion of this *internal* practice step, staff members conducting patient tests should have a comprehensive understanding of the device and the ability to accurately perform a patient test and record results. Testing staff should be well-versed on positioning patients, demonstrate the ability to read and record the patient test results, and troubleshoot errors that may intermittently occur, using the provided reference materials for support.

Staff should also be familiar with standard device maintenance tasks for optimal upkeep.

Typically, Step #2 is successfully completed within days 11-20 of receiving the DPNCheck device.

3 As the final step of staff training, the local Program Lead will accompany each testing medical staff member as they perform the DPNCheck test on their first patient. The Program Lead will ensure that the medical staff is performing the DPNCheck test correctly end-to-end, including patient interactions and properly setting patient expectations.

Quick reminders while preparing the patient for a DPNCheck test:

- Notify the patient that their doctor has ordered the test to check their nerve health
- The test takes approximately 20 seconds to complete
- The device will stimulate at their ankle about 10 times, with each stimulus feeling like a buzz or possibly like a snapping rubber band
- Remind the patient to remain still during the short test
- Ask the patient if they have any questions before the test begins
- Inform the patient when the test will begin

At the conclusion of this training step, passing staff may be awarded a training certificate by the Program Lead recognizing their demonstrated competency in patient testing. **Typically, Step #3 is successfully completed within days 21-31 days of receiving the DPNCheck device.**

***Tip: Helpful online resource documents available for additional support and download:**
www.DPNCheck.com/training

1. DPNCheck Product Brochure
2. DPNCheck 2.0 (Model NC-040) User Manual Online
3. DPNCheck 2.0 Device Reference Guide (includes Troubleshooting & Test Results)
4. DPNCheck Sural Nerve Conduction Guide *(without age/height adjustment)*
5. Patient Positioning Guide

Pro Tips

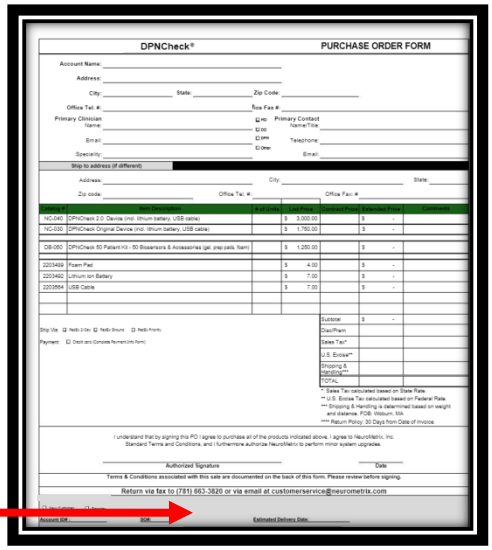
Maintenance, Cleaning & Reuse:

- The biosensor is intended for single patient use and *must be* changed between each patient.
- The biosensor may be used to test the other leg on the on the **same** patient.
- Unless the foam is contaminated, it does *not* require cleaning. Replace foam when the foam is no longer sticky. Save the foam liner to protect foam when device is not in use.
- Device probes are to be cleaned between each patient test.
    - Wipe away excess gel
    - Check temperature lens between probes for gel and wipe away
- Soft cloth wipe or isopropyl alcohol can be used to clean the device exterior, as needed. Do **not** use strong solvents or abrasive cleaners.
- When cleaning the prongs of the device, remember to start the wipe at the base of the prong and wipe straight and **gently** away from the device. Do **not** twist the wipe on the prong, as there are wires attached to the end of the prongs.

Supply Ordering

Reordering and replenishment of accessories and supplies has been established by your corporate office. It is recommended that one (1) box of back up biosensors, per device, is kept on hand in addition to back up batteries.

Please adhere to your established corporate policy for ordering protocols. If submitting Purchase Orders directly; please be sure complete ***and sign*** each Purchase Order prior to sending. Please send to Customer Service: **customerservice@dpncheck.com** receipt, a confirmation of the order will be acknowledged via email. As an alternative, fax orders can be sent to **844.DPN.CHECK (844.376.2432)**. Successfully processed orders should arrive business hours. The same PO form can be used for reorders.


DPNCheck®

PURCHASE ORDER FORM

Account Name:

Address:

City: State: Zip Code:

Office Tel. #: Fax #:

Primary Clinician Name: Primary Contact Name/Title

Email: Telephone:

Specialty: Email:

Ship to address (if different)

Address: City: State:

Zip code: Office Tel. #: Office Fax #:

Item #	Item Description	Unit	List Price	Discount Price	Extended Price	Comments
NC-040	DPNCheck 2.0 Device (incl. lithium battery, USB cable)		$ 3,000.00		$ -	
NC-030	DPNCheck Original Device (incl. lithium battery, USB cable)		$ 1,750.00		$ -	
DB-050	DPNCheck 50 Patient Kit - 50 Biosensors & Accessories (gel, prep pads, foam)		$ 1,250.00		$ -	
2203489	Foam Pad		$ 4.00		$ -	
2203492	Lithium Ion Battery		$ 7.00		$ -	
2203564	USB Cable		$ 7.00		$ -	

Subtotal $ -

Disc/Prem

Sales Tax*

U.S. Excise**

Shipping & Handling***

TOTAL

* Sales Tax calculated based on State Rate.
** U.S. Excise Tax calculated based on Federal Rate.
*** Shipping & Handling is determined based on weight and distance. FOB: Woburn, MA
**** Return Policy: 30 Days from Date of Invoice

I understand that by signing this PO I agree to purchase all of the products indicated above. I agree to NeuroMetrix, Inc. Standard Terms and Conditions, and I furthermore authorize NeuroMetrix to perform minor system upgrades.

Authorized Signature Date

Terms & Conditions associated with this sale are documented on the back of this form. Please review before signing.

Return via fax to (781) 663-3820 or via email at customerservice@neurometrix.com

Account #/#: SO#: Estimated Delivery Date:

STANDARD TERMS AND CONDITIONS

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1. ORDER/DELIVERY. Purchase orders shall be binding on Buyer when issued to Seller, but shall not be binding on Seller unless and until Seller has accepted such purchase order by written acceptance or by shipping the ordered Products. For avoidance of doubt, the sale of any consumable/disposable Products sold for use with other Products under these Terms and Conditions shall be subject to these Terms and Conditions even if the sale of such consumable/disposable Products is not pursuant to a formal purchase order referencing these Terms and Conditions. Shipment will be made in a manner determined by Seller. All prices are F.O.B. Seller's place of shipment with shipping and handling fees prepaid and added to the invoice amount, unless otherwise expressly agreed by Seller. Title and risk of loss or damage to the Product shall pass to the Buyer at the same time Seller delivers possession of the Product to a carrier at Seller's place of shipment, except that any software provided with or as part of such Product is licensed nonexclusively solely for use with or as part of such Product, as the case may be, and is not sold.

2. PAYMENT TERMS. Buyer shall pay the invoiced amount via credit card in advance of shipment, unless otherwise expressly agreed by the parties. Where other terms are agreed by the parties, Seller may assess reasonable costs of collection and an interest charge of up to one and on half percent (1.5%) per month on all amounts which are not timely paid (but not to exceed the maximum lawful rate). Buyer hereby grants to Seller a purchase money security interest in the Product to secure the purchase price of the Product until the purchase price is paid in full. Buyer agrees to execute and deliver all documents requested by Seller to perfect and maintain Seller's security interest.

3. TAXES, DUTIES, LEVIES AND SIMILAR CHARGES. The prices quoted do not include any applicable duties or sales, use, excise, value added or similar taxes or governmental charges now or hereafter in effect with respect to the Products, or the shipment or use thereof, all of which duties, taxes and charges shall be the responsibility of, and shall be paid by Buyer. Seller may collect sales tax in certain states, as indicated on the invoice.

4. WARRANTY. Seller makes only those warranties with respect to Product expressly identified in writing as "warranties" and set forth in Seller's current operating manual or catalogues, or in specific written warranty included with the shipment of the Product, in any (the "Express Warranty"). Except as expressly set forth above, SELLER, AND ITS AFFILIATES, SUBCONTRACTORS AND SUPPLIERS, PROVIDE THE PRODUCT "AS IS" AND TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAW, SPECIFICALLY DISCLAIM ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR NONINFRINGEMENT. BUYER'S SOLE AND EXCLUSIVE REMEDY FOR BREACH OF WARRANTY SHALL BE SELLER'S OBLIGATION TO REPAIR OR REPLACE THE PRODUCT OR PROVIDE A REFUND AS SET FORTH IN THE EXPRESS WARRANTY.

5. RESTRICTIONS. Buyer shall comply with all laws rules and regulations applicable to the use, distribution, exportation, marketing and promotion of Products and services using the Products. Further, Buyer shall use and promote the Products, and services using the Products, solely in accordance with any instructions provided by Seller, and solely for the uses stated on the Product label or in the Product manual, if any.

6. INDEMNITY/LIMITATIONS OF LIABILITY. Seller shall not be responsible for any loss or injuries caused by the use of the Products by Buyer or its affiliates, personnel, customers, or agents. Buyer agrees to indemnify, defend and hold Seller, and its officers, directors, affiliates, contractors and suppliers, harmless against any suits, claims, damages, costs and expenses, arising out of any breach of the Terms and Conditions, or use of the Products by Buyer or its affiliates, personnel, customers or agents, except to the extent caused by the negligence or misconduct of the Seller. TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAW, (A) SELLER SHALL NOT BE LIABLE FOR INCIDENTAL, INDIRECT, SPECIAL, EXEMPLARY OR CONSEQUENTIAL DAMAGES INCLUDING, BUT NOT LIMITED TO, LOSS OR GOODWILL OR REPUTATION, LOST PROFITS, SAVINGS OR REVENUES OF ANY KIND, WHETHER OR NOT SELLER HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES, UNLESS OTHERWISE CONTRARY TO STATE LAW; AND (B) SELLER'S AGGREGATE LIABILITY SHALL NOT EXCEED THE PURCHASE PRICE OF THE PRODUCTS.

7. MISCELLANEOUS. Product returns must made within thirty (30) days from the date of Seller's invoice for Standard Return. Otherwise, products may not be returned except during the Express Warranty period if non-compliant with the Express Warranty. Any returns require an RMA number issued by Seller. Buyer shall not assign these Terms and Conditions or any rights or obligations hereunder without the prior written consent of Seller. Any attempted assignment without Seller's consent shall be void and ineffective. These Terms and Conditions and all transactions hereunder shall be governed by the laws of the Commonwealth of Massachusetts excluding its choice of law rules and excluding the United Nations Conventions on Contracts for the International Sale of Goods. The parties irrevocably consent to the exclusive jurisdiction of, and venue in, the federal and state courts in Massachusetts. By accepting delivery of these goods, Buyer waives any objections to this choice of law and exclusive forum selection. If any provision hereof, or the application of such provision to any person or circumstance is held invalid or unenforceable in any jurisdiction, the remaining provisions or the application of such provision to person or circumstances other than those as to which it is held invalid or unenforceable, or in other jurisdictions, shall not be affected thereby. These Terms and Conditions supersede all prior oral or written understandings between the parties and shall constitute the entire agreement between the parties with respect to the subject matter of these Terms and Conditions. These Terms and Conditions shall not be modified or amended except by a writing signed by Buyer and Seller.

Common Reorder Items:

NC-040	DPNCheck 2.0 Device (inc: lithium battery & USB cable)
DB-050	DPNCheck 50 Patient Kit (inc: 50 single-use biosensors, gel, prep pads, foam)
2203489	Foam Pad (individually ordered if the adhesive is no longer sticking to the device)
2203492	Lithium Battery (3V disposable Panasonic battery CR123A). **Note: Life of battery varies however, generally conducts ~100 tests*
2203564	USB C Cable

***Tip: Helpful online clinical documents and resources available for download: www.DPNCheck.com/training**

1. CLINICAL PROVIDER Education Presentation/Multiple Videos
2. DPNCheck Normative Data
3. CLINICAL PROVIDER Publications
4. Undetectable Result Video
5. Peripheral Neuropathy Patient Brochure

Reporter Software Installation

Your corporate office will provide guidance on the Reporter software installation and configurations. If you have additional questions, please reach out to your local IT lead.

[See Best Practices and Operational Workflows for DPNCheck Reporter]

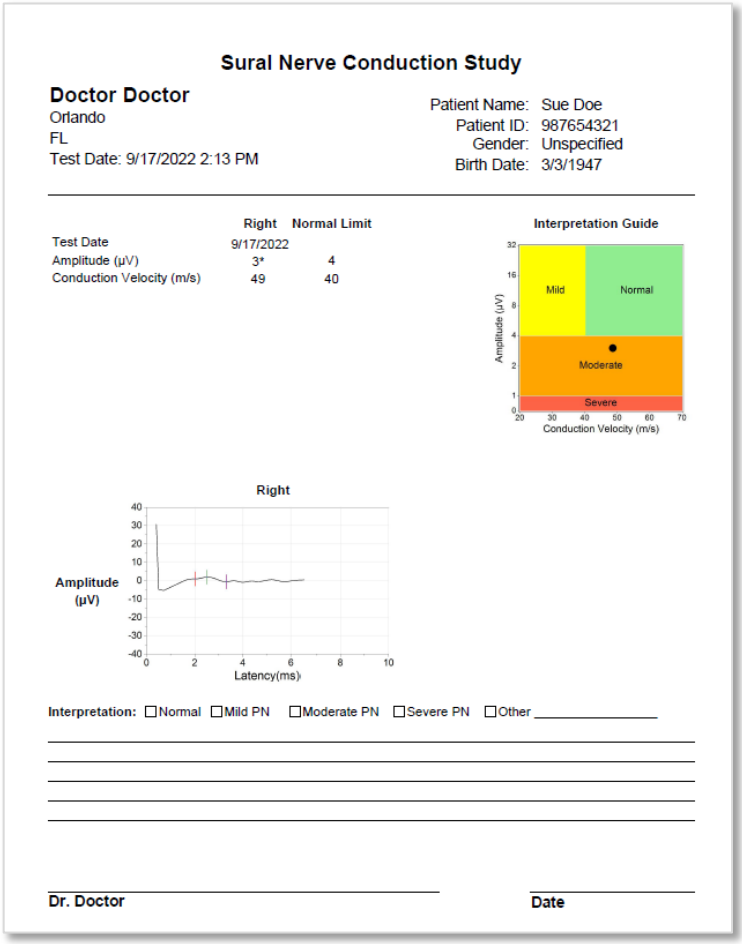
Reporter software provides:

- Hard copy or PDF report with waveforms and patient results
- Automated comparisons to normal limits
- Data archive
- HL7 data output for EMR integration

Note: due to patient privacy, DPNCheck prsonnel are not able to "remote" into Partner systems for troubleshooting.

TEST RESULTS:

The report includes the sural nerve amplitude and conduction velocity, expected "normal" values, and the nerve response waveforms. The report documents the patient's peripheral nerve function.



Sural Nerve Conduction Study

Doctor Doctor
Orlando
FL
Test Date: 9/17/2022 2:13 PM

Patient Name: Sue Doe
Patient ID: 987654321
Gender: Unspecified
Birth Date: 3/3/1947

	Right	Normal Limit
Test Date	9/17/2022	
Amplitude (µV)	3*	4
Conduction Velocity (m/s)	49	40

Interpretation Guide

Right

Interpretation: ☐Normal ☐Mild PN ☐Moderate PN ☐Severe PN ☐Other _____

Dr. Doctor

Date

Clinical interpretation is typically straightforward. Clinical interpretation is the responsibility of a physician or another appropriately credentialed provider. Please note, if the corporate office has selected settings to adjust for age and height the normative values for amplitude and conduction velocity will vary.

***Tip: Helpful online documents available for download: www.DPNCheck.com/training**

1. DPNCheck Reporter Software Download
2. DPNCheck Reporter Software User Manual
3. Sural Nerve Conduction Test Report Sample PDF