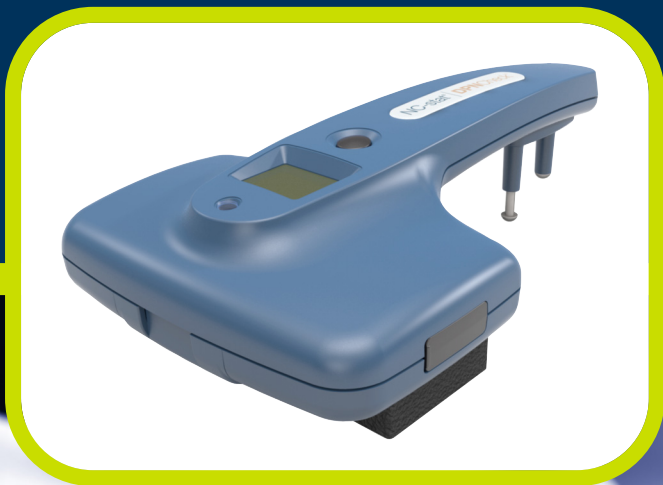


NC-stat® | **DPNCheck™**

User Manual



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NEUROMetrix®

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CHAPTER ONE: INTRODUCTION

1.1 Indications For Use

The NeuroMetrix NC-stat® | DPNCheck™ is intended to measure neuromuscular signals that are useful in diagnosing and evaluating systemic and entrapment neuropathies.

1.2 Contraindications

None.

1.3 Warnings, Precautions & Safety Considerations

- Federal law restricts this device to sale or use by or on the order of a health care provider appropriately licensed by the law in the state in which they practice
- For safe and effective operation of the device, please read and understand the User Manual thoroughly
- Use the device only as described in this manual
- Failure to follow the Warnings listed below may cause injury to the patient or operator
- Possible hazard of fire or explosion. Use care when operating this device close to oxygen sources, flammable gases, and chemicals
- Patients with implanted electronic devices should not be subjected to electrical stimulation unless specialist medical opinion has first been obtained
- Avoid accidental contact with connected but unapplied conductive components, including electrodes
- Do not place any part of the device over broken skin, lesions, or wounds

1.4 Overview

The NC-stat DPNCheck device measures the sural nerve conduction velocity and sensory nerve action potential (SNAP) amplitude. The device includes the following elements:

- **Power/Test Button** – allows users to turn the device on and initiate a test.
- **LCD Display** – area where test results and error messages are displayed.
- **LED Light** – status indicator.
- **Battery Compartment** – holds 3V Lithium battery that powers device.
- **Biosensor Port** – where the biosensor is connected to the device.
- **Infrared Thermometer** – reads the patient's skin surface temperature.
- **Stimulating Probes** – non-invasively deliver electrical stimulation to the sural nerve.
- **Biosensor** – a single patient-use biosensor is needed to conduct each test.
- **USB Port** – for communication with a PC.



CHAPTER TWO: SETUP

2.1 Package Contents

Prior to use, the package should be inspected to ensure that all of the following components are included and undamaged.

STANDARD COMPONENTS:

- NC-stat DPNCheck device
- 3V Lithium Battery
- USB Cable

2.2 Reporting Damage

If any of the components appear to be damaged, or if the NC-stat DPNCheck device fails to operate as described in this manual, contact NeuroMetrix immediately. Within the USA, customers should contact NeuroMetrix Customer Service:

Phone: (888) 786-7287

Fax: (781) 663-3820

E-mail: customerservice@neurometrix.com

International customers should contact the nearest authorized NeuroMetrix representative. If the shipping container is damaged, customers should also notify the shipping carrier.

2.3 Battery Installation

The NC-stat DPNCheck device uses a standard 3V Lithium Ion Battery (Type CR123A).

1. Remove the battery cover on the backside of the device.
2. Insert the battery. Check the battery symbol inside the device to ensure proper orientation of positive and negative contacts.
3. Replace the cover.


2.4 Registration

In order to activate your warranty, receive software updates, and use various optional reporting and data management services, you must register your device with NeuroMetrix. Call NeuroMetrix Customer Service (888) 786-7287 to register the device's serial number. The serial number is an 8 digit number (e.g., 11110001) found inside the battery compartment.

CHAPTER THREE: OPERATING INSTRUCTIONS

This chapter explains the basic operation of the NC-stat DPNCheck device.


3.1 Power On

To power on the device, press the grey button under the LCD Display Screen. The green light will blink once to indicate power on and  indicates that the device is ready for use.

3.2 Power Off










The device will power off automatically after 10 minutes of inactivity. Note: Your last test is saved on the device until a new test is performed.

3.3 Battery Lifetime

The NC-stat DPNCheck is powered by a 3V Lithium Ion Battery. A solid amber light will indicate that the battery is low and should be replaced as soon as you complete the test in progress. A solid red light accompanied by  indicates that the battery must be replaced before any further testing. See section 2.3 for battery installation.

3.4 Test Procedure

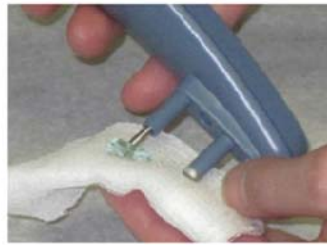
Proper patient positioning, skin preparation, and device placement are essential to accurately administer the test. The section below will demonstrate proper techniques.

| | | |
|--|--|--|
|  |  |  |
| <p>Step 1: Lay the patient on an exam table and prepare the testing area with a Preparation Pad.</p> | <p>Step 2: Power on the device. The display will show  and the light will turn amber  or red  when the battery needs to be replaced.</p> | <p>Step 3: Fully insert the biosensor into the port. The light will turn green  once the biosensor has been properly inserted. Align to foam. The display will show  to set the leg to be tested.</p> |
|  <p>Tip: Both the outer ankle bone (lateral malleolus) and Achilles tendon should be easily accessible as shown at left. Please reference the User Manual for alternative patient positions.</p> <p>The test area should be vigorously scrubbed with the Preparation Pad provided.</p> | <p>Tip: Align the biosensor with the foam on all sides; "REMOVE BACKING" label side faces up.</p> | |



Step 4: Set the leg to be tested. The device display screen will blink with the leg selected (l = left; r = right). To switch the leg, hold the button down for 1-2 seconds and the selection will change to the opposite leg.

Tip: Whenever possible, test the same leg in all patients.

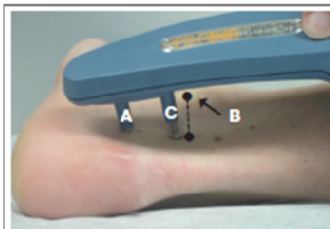


Step 5: Apply a small amount of conductive gel to each probe. The head of the probe should be covered with gel.

Tip: Remove excess gel that may lead to gel smearing between the two probes.



Step 6: Remove the backing from the biosensor.

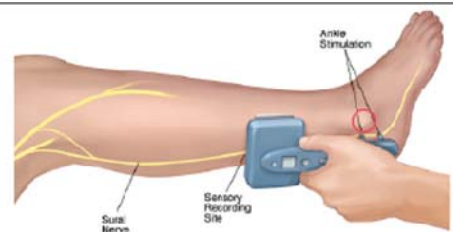


Step 7: Locate the patient's outer ankle bone to align the long probe just behind it.

Tip: The anode (short probe, **A**) and cathode (long probe, **C**) should be aligned to the outer ankle bone, **B**. The cathode should be adjacent to the middle (central prominence) of the ankle bone. The nerve is stimulated only under the cathode.



Step 8: Align the device on the lower calf by pushing down firmly on the foam. The device should point towards the back side of the knee with the **inner edge of the biosensor placed next to the midline** (Achilles tendon). Ensure that the device is aligned to but does not cross over the midline as shown by the dashed line in the image above.



Tip: The probes should be placed behind but not over the outer ankle bone.

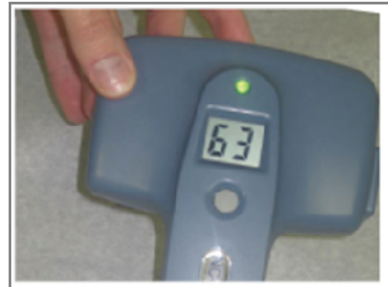


Tip: Check for good contact on both sides of the foam.



Step 9: Press the button to start the test. The light will blink with each stimulation. Limb selected will be displayed.

Tip: During test, maintain:
 a.) Firm pressure on **probes**
 b.) Firm pressure on **biosensor**
 c.) **Steady** positioning



Step 10: Maintain constant force throughout the test. The test time may vary per patient, but normally lasts for 10-15 seconds. The results will display once completed.

Patient Positioning

The preferred position is for the patient to lie on their side on an exam table with the leg to be tested on top (Figure 1). If you cannot see both the outer ankle bone and the calf midline (Achilles tendon), adjust patient position to their appropriate side. The patient should be in a comfortable position that allows for relaxation of the leg and foot. It is important that the patient remains relaxed during the test.

Alternative positions may include: side with left leg extended (Figure 2); prone with feet hanging off the exam table (Figure 3); and chair with one leg resting on a chair (Figure 4). The patient should bend their knee and place half of their calf on to the seat in order for the leg to be properly rested and grasp the back of the chair for stability. It is recommended that a sturdy chair with no wheels and a padded seat be used for patient comfort. Note: Users should only use a chair when an exam table is not available.

Figure 1: Alternative position; side



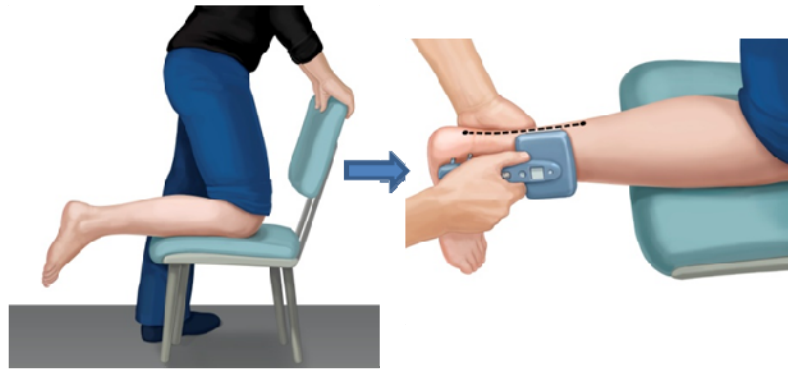
Figure 2: Alternative position; side



Figure 3: Alternative position; prone



Figure 4: Chair; leg up



3.5 Test Results

When the test is complete, the device display will toggle between the sural nerve conduction amplitude in microvolts (μV) and the conduction velocity in meters per second (m/s). In cases where the patient has low amplitude (between 2-4 μV) and the CV cannot reliably be reported, only the amplitude will display on the device. Amplitude result is indicated by a decimal point at the upper right corner of the screen.

| Display Example | Result | Actions |
|-------------------------|---|---|
| 40 | Conduction Velocity – meters/second | Record and interpret result. |
| 4* | Amplitude – microvolts* | Record and interpret result. |
| 0* | Undetectable Response; no Conduction Velocity displayed | Record and interpret result. |
| Pn Pr Sn Lb Ec °C Hd | Test Unsuccessful | Note displayed code and refer to Troubleshooting on back. |

Recalling Results on Device

If the device powers down after a test, the results of that test can be recalled. To recall the results press and hold the button for 3 seconds and you will see the results appear on the display. Results will display for 10 seconds and then the device will power off. This mode can only be accessed when the device is powered off. If you have powered on the device and need to recall the last result, wait 3 minutes for the device to power down and then follow the instructions above for recalling results.

3.6 Recommended Testing Protocol

This protocol is intended only as a guide. It is the responsibility of the provider to determine the clinical necessity of nerve conduction testing.

Testing a single leg is usually clinically sufficient.

- Whenever possible, the same leg should be tested first in all patients.

If the first test does not provide a result or to confirm the result, the test should be repeated.

- Pressing the test button again is usually all that is required (see Appendix F).

The test will provide a nerve conduction result the first time in most patients.

Tip: In certain circumstances it may be beneficial to confirm the results. Examples include:

- Confirm CV if amplitude is $\leq 4 \mu\text{V}$
- Confirm undetectable response
- Confirm result inconsistent with clinical findings
- If the leg setting on the device was incorrect, then the test should be repeated

If the repeat test does not provide a result or for further confirmation of the results the opposite leg should be tested.

- The same biosensor may be used on both legs.

Note: The NC-stat DPNCheck device should only be used with NeuroMetrix single patient use biosensors. Repeat use of the same biosensor on multiple patients will disable the device as indicated by the "Ub" error code. Disabled devices must be returned to NeuroMetrix for a factory reset. Users will be required to pay a service fee and all shipping and handling charges.

CHAPTER FOUR: SAFETY, WARRANTY SERVICE, CARE, AND SERVICE

4.1 Safety Notes

Do not immerse any portion of the NC-stat DPNCheck device in water or other fluids. Avoid spilling fluids on the Device or accessories. Spilling fluids may damage the device and/or present a fire or shock hazard.

Possible hazard of fire or explosion. Use care when operating this device close to oxygen sources, flammable gases, and chemicals.

Failure to follow the Cautions listed below may change the performance of the equipment, or cause damage to the equipment.

Radio frequency (RF) interference from devices such as cellular phones and two-way radios may cause improper operation of the NC-stat DPNCheck device if used in close proximity.

Accessory equipment connected to the USB port must be certified according to the respective IEC standards (e.g. IEC60950 for data processing equipment and IEC60601-1 for medical equipment). Most computers manufactured by major suppliers meet the IEC60950 standard. If in doubt, consult your local Information Technology support.

4.2 Maintenance and Cleaning

Other than changing the battery, there are no user serviceable parts inside the NC-stat DPNCheck device. Refer to the warranty and service information included in this manual.

The NC-stat DPNCheck device has been manufactured to the highest quality standards. To ensure continued trouble-free operation, avoid exposing the components to excessive shock, vibration, or moisture.

Cleaning the device and any components:

- Remove the battery and close the battery compartment and any other external connections before cleaning the Device or any of the components.
- Use a soft damp cloth or sponge to clean the exterior of the unit.
- Do not use abrasive cleaners or strong solvents to clean the device.

Disinfecting the NC-stat DPNCheck device:

- If the NC-stat DPNCheck device becomes contaminated by body fluids, it should be cleaned using a hospital grade disinfectant and a disposable, soft cloth or paper towel, per standard hospital or office protocol.

4.3 Use of and Disposal of Batteries

The battery is a 3.0V Lithium Battery type CR123A. Dispose of used Lithium battery in accordance with national, regional, and local regulations.

4.4 Storage of Biosensors

NC-stat DPNCheck biosensors are single-use, non-sterile devices. They should be stored lying flat at room temperature in a dry location. Storage temperature should not fall below -22° F (-30° C) or exceed 140° F (60° C). The package should only be opened immediately prior to use. The biosensors should not be used after the expiration date shown on the package.

4.5 NeuroMetrix, Inc. Limited One Year Warranty

NeuroMetrix, Inc. manufactures its hardware products from new components in accordance with industry standard practices. NeuroMetrix warrants the NC-stat DPNCheck device to be free from defects in materials and workmanship. The warranty term is one year beginning on the date of invoice, as described in the following text.

Damage due to shipping the products is covered under this warranty. Otherwise, this warranty does not cover damage due to external causes, including accident, abuse, misuse, problems with electrical power, servicing not authorized by NeuroMetrix, Inc., usage not in accordance with product instructions, failure to perform required preventive maintenance, and problems caused by use of parts and components not supplied by NeuroMetrix, Inc.

This warranty does not cover any items that are in one or more of the following categories: software, external devices (except as specifically noted) or accessories or parts added to a NeuroMetrix device through authorized NeuroMetrix service centers.

NeuroMetrix, Inc., will repair or replace products covered under this limited warranty that are returned to NeuroMetrix's facility or an authorized NeuroMetrix representative. To request warranty service, you must call the NeuroMetrix Customer Service at (888) 786-7287 or call an authorized technical support representative within the warranty period. NeuroMetrix will issue a Return Material Authorization (RMA) Number. The product must be shipped to NeuroMetrix in the original or equivalent packaging, with prepaid shipping charges, and insured against loss or damage during shipment. NeuroMetrix will ship the repaired or replacement units to the originator (freight prepaid) to addresses within the US or Canada. Shipments to other locations will be made freight collect.

All parts removed from repaired products will become the property of NeuroMetrix, Inc. If NeuroMetrix repairs or replaces a product, the original warranty is not extended.

NEUROMETRIX, INC. MAKES NO EXPRESS WARRANTIES OR CONDITIONS BEYOND THOSE STATED IN THIS WARRANTY STATEMENT. NEUROMETRIX DISCLAIMS ALL OTHER WARRANTIES AND CONDITIONS, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION IMPLIED WARRANTIES AND CONDITIONS OR MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. SOME STATES (OR JURISDICTIONS) DO NOT ALLOW LIMITATIONS ON IMPLIED WARRANTIES OR CONDITIONS, SO THIS LIMITATION MAY NOT APPLY TO YOU.

NEUROMETRIX'S RESPONSIBILITY FOR MALFUNCTIONS AND DEFECTS IN HARDWARE IS LIMITED TO REPAIR AND REPLACEMENT AS SET FORTH IN THIS WARRANTY STATEMENT. THESE WARRANTIES GIVE YOU SPECIFIC LEGAL RIGHTS IN ADDITION TO OTHER RIGHTS WHICH VARY FROM STATE TO STATE.

NEUROMETRIX INC. DOES NOT ACCEPT LIABILITY BEYOND THE REMEDIES SET FORTH IN THIS WARRANTY STATEMENT OR LIABILITY FOR INCIDENTAL OR CONSEQUENTIAL DAMAGES, INCLUDING WITHOUT LIMITATION ANY LIABILITY FOR PRODUCTS NOT BEING AVAILABLE FOR USE OR FOR LOST DATA OR SOFTWARE.

These provisions apply to NeuroMetrix's limited one-year warranty only.

4.6 Service

Should the NC-stat DPNCheck device require service, contact NeuroMetrix Customer Service at (888) 786-7287. When you call NeuroMetrix to request service, please be prepared to provide the following information:

- Serial number
- Description of the problem

Do not return any component of the NC-stat DPNCheck device without first obtaining a Return Material Authorization (RMA) Number from Customer Service. Be sure that this number is clearly visible on the exterior of the return package. If a NC-stat DPNCheck device component must be shipped to a service center, pack it in the original shipping container or in packaging which provides enough protection to prevent damage during shipment.

4.7 FDA Notification

The NC-stat DPNCheck device is manufactured in compliance with the U.S. Federal Quality System Regulation (21 CFR Part 820). As a health care provider, you may have responsibilities under the Safe Medical Devices Act (SMDA) for reporting to NeuroMetrix, and possibly the FDA, the occurrence of certain events. (FDA reportable events are detailed in 21 CFR Part 803.)

In accordance with our Quality System, NeuroMetrix should be notified of any device failures or malfunctions. Issues encountered should be reported to NeuroMetrix Customer Service. Outside of the United States, problems should be reported to the nearest NC-stat DPNCheck device distributor. This information will help ensure that NeuroMetrix continues to provide products and services of the highest possible quality.

Appendix A: SPECIFICATIONS
Dimensions

| | |
|-------------|----------------------------|
| Device Size | 5.5 cm x 19.0 cm x 11.6 cm |
| Weight | 160 g |

Environmental - Shipping and Storage

| | |
|-------------|----------------------------|
| Temperature | -20 °C to 50 °C |
| Humidity | 10% to 90%, non-condensing |
| Altitude | 55 kPa to 100 kPa |
| Operating | 10 °C to 30°C |

Hardware

| | |
|----------------------------------|--|
| Channels | 2 |
| CMRR (typical) | ≥ 100 dB |
| Gain | x977 |
| Noise (typical) | < 2 μV rms |
| Frequency Response | (-3 dB) 2 Hz – 2 kHz |
| Sampling Frequency | 10 kHz |
| ADC Resolution | 16 bits (effective) |
| Stimulator Type Constant Current | Monophasic |
| Stimulator Max Voltage (typical) | 420 V |
| Stimulator Max Current | 100 mA hardware, software limited to 70 mA |
| Stimulator Pulse Width | 100 μs |
| Stimulation Frequency | 1 Hz (maximum) |
| Skin Temperature Measurement | Non-contact, infrared |
| Battery | 3.0 V Lithium Primary (CR123A) |
| LCD Display | 2 digit, 7-segment |
| Water Resistance | IEC 529 IPX0 not protected from ingress of liquids |
| Classification Type | BF Applied Part, IEC 60601-1 |

Neurophysiology

| | |
|---------------------------------|--|
| Nerve | Sural sensory, orthodromic |
| Methodology | Preconfigured electrode array |
| Stimulation Site | Behind lateral malleolus |
| Stimulation Configuration | Bipolar (2 cm separation) |
| Recording Site | 9.22 cm proximal to stimulation |
| Recording Configuration | Bipolar (2 cm separation) |
| Conduction Velocity (CV) | Onset of negative deflection (m/s) |
| Response Amplitude | Peak to peak (μV) |
| Temperature Compensation Method | Linear, 1.0 m/s per degree, maximum correction 5 m/s |
| Reference Temperature | 28 °C |

Appendix B: SYMBOLS

Attention/User Manual/device labeling



Type BF Applied Part



0123

Mark identifying compliance with council directive 93/42/EEC

Identification mark of the Notified Body, TUV SÜD
responsible for evaluation of the CE Technical File.



WEEE (Waste Electronic and Electrical Equipment) symbol in accordance
with council directive 2002/96/EC



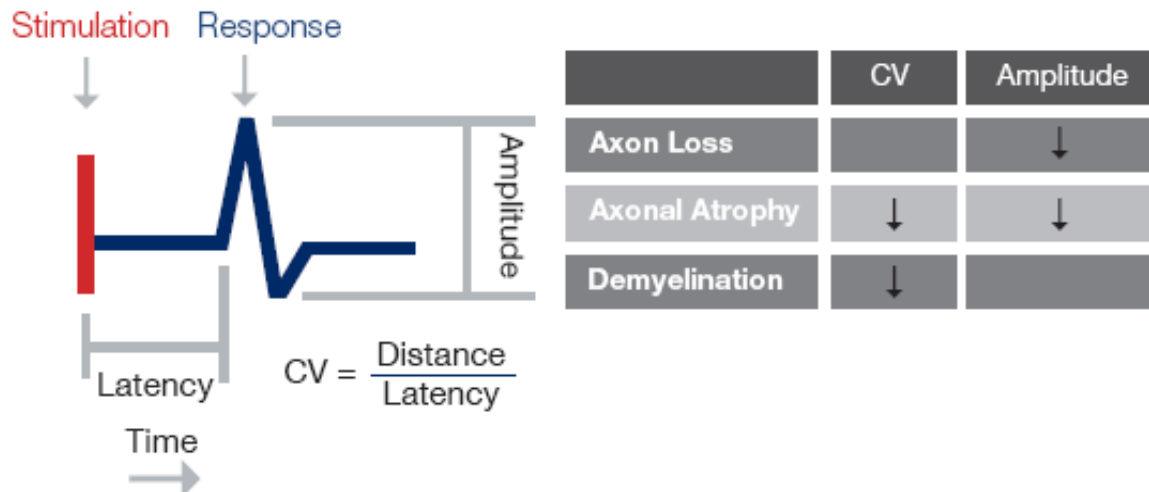
MN

Abbreviation for model number

Appendix C: SENSORY NERVE CONDUCTION PRINCIPLES & NERVE CONDUCTION TERMINOLOGY

Sensory Nerve Conduction Principles

Sensory nerve conduction measures function of large myelinated axons – light touch, proprioception, vibration, and pressure sensation



Nerve Conduction Terminology

Amplitude – size of nerve response (microvolts, μV)

Conduction Velocity (CV) – speed of nerve response propagation (meters per second, m/s)

Latency – time between nerve stimulation and detection of response

Distance – propagation distance between site of nerve stimulation and response detection (9.22 cm)

Response – bioelectrical nerve response, typically $<50 \mu\text{V}$

Stimulation – electrical stimulation of nerve, typically 20 – 60 milliamps for 100 microseconds

Undetectable – nerve response amplitude is below the threshold of electronic detection, displayed as amplitude $0 \mu\text{V}$

Appendix D: USB CONNECTION

Uploading Data


The most recent test results may be uploaded to your PC using a USB cable. A mini-USB port is located on the side of the device. The device can only retain data from a single test. Users must upload the data after each test for report generation. Note: If the device powers off before performing an upload, the data is still saved on the device and may be uploaded.

1. Power on the device.
2. Open the USB port located on the side of the device.
3. Ensure that the Communicator application is open on the PC.
4. Connect the USB cable to the device and PC.
5. After connecting the device to the PC with the USB cable, the device LCD screen will display PC.
Note: If the red light on the device appears during this step, the data could not be transferred. See Appendix F for Troubleshooting.

Appendix E: TEMPERATURE COMPENSATION

Nerve conduction measurements may be sensitive to the temperature around the nerve, which in superficially located nerves (e.g., sural), may be different than body temperature. Nerve temperature is usually approximated by the skin surface temperature overlying the nerve.

The NC-stat DPNCheck device compensates for the effect of temperature on sural nerve conduction velocity using a linear temperature compensation factor of 1 m/s per °C with a reference temperature of 28 °C. The effect of temperature on sural nerve conduction amplitude is small and therefore compensation is not applied for this parameter. The temperature is measured by an infrared thermometer, located at the base of the handle behind the stimulating probes.

If the temperature is below 23 °C, then the patient is too cold to reliably measure nerve conduction and the test will stop with  displayed on the LCD screen.

Appendix F: TROUBLESHOOTING

| Display | Light | Description | Possible Causes | Solution |
|---------|-------|--|--|---|
| Lb | ● | Data quality issue | <ul style="list-style-type: none"> Incorrect limb setting on device. | <ol style="list-style-type: none"> Ensure that the limb setting on the device is correct. If incorrect, re-select the limb on the device by pressing the button down for 1-2 seconds until correct limb is selected (l = left; r = right). Retest. |
| Pn | ● | Data quality issue | <ul style="list-style-type: none"> Adequate signal could not be recorded. | <ol style="list-style-type: none"> Confirm placement and retest. |
| Pr | ● | Stimulation issue | <ul style="list-style-type: none"> Insufficient gel on probes. Poor contact of probes with skin. Inadequate skin preparation in probe contact area. Probe movement during test. Gel smeared between the probes. | <ol style="list-style-type: none"> Re-do skin preparation and device placement. <ul style="list-style-type: none"> Clean probes and re-apply gel. Vigorously scrub the ankle area. Reposition the device on the patient with firm pressure to both probes and on biosensor. Retest with constant force to limit device movement during test. |
| Sn | ○ | Biosensor disconnected during test | <ul style="list-style-type: none"> Biosensor disconnected during test. | <ol style="list-style-type: none"> Re-insert biosensor with tail traces facing outward. <ul style="list-style-type: none"> Entire biosensor tail must be inserted. If problem persists, replace biosensor. |
| Sn | ● | Data quality issue | <ul style="list-style-type: none"> Biosensor backing not removed. Incomplete biosensor contact. Skin in biosensor contact area inadequately prepared. | <ol style="list-style-type: none"> Remove biosensor backing and retest. <ul style="list-style-type: none"> Check for good contact on <u>both sides</u> of the foam. If problem persists, re-prepare skin and replace with new biosensor. Retest. |
| Ec | ● | Data quality issue | <ul style="list-style-type: none"> Signal contamination due to patient movement or excessive muscle contraction. | <ol style="list-style-type: none"> Confirm that the patient is relaxing leg muscles. Reposition patient if necessary. Retest. |
| Ec | ● | Data quality issue | <ul style="list-style-type: none"> Biosensor backing not removed. | <ol style="list-style-type: none"> Remove biosensor backing and retest. |
| oC | ● | Patient ankle cold | <ul style="list-style-type: none"> Temperature detector field of view obstructed. Patient's ankle temperature <23°C. | <ol style="list-style-type: none"> Ensure that tester's hand does not obstruct temperature detector. Warm patient's lower leg by: <ul style="list-style-type: none"> putting a sock on and elevating the leg. <ul style="list-style-type: none"> If unsuccessful: <ul style="list-style-type: none"> instruct the patient to put on their shoes and socks then walk around for 1-2 minutes if able. OR <ul style="list-style-type: none"> wrap the patient's lower leg and ankle with a blanket or heating pad. OR <ul style="list-style-type: none"> briskly rub the patient's lower ankle. (Note: Although it is not an ideal approach, this technique can be used if the tester is in a hurry.) Retest. |
| Lo | ● | Low battery | <ul style="list-style-type: none"> Battery is low. | <ol style="list-style-type: none"> Replace battery. |
| Hd | ● | Device hardware issue | <ul style="list-style-type: none"> Device hardware issue. | <ol style="list-style-type: none"> Contact Customer Service. |
| Ub | ● | Excessive biosensor reuse detected. Device is disabled | <ul style="list-style-type: none"> Excessive biosensor reuse detected. Excessive repeat testing. | <ol style="list-style-type: none"> Contact Customer Service. |

Appendix G: MANUFACTURER'S DECLARATIONS OF CONFORMITY

(in accordance with ISO/IEC 17050-1 and ZLG 3.9 A 4)

MANUFACTURER

NeuroMetrix, Inc
62 Fourth Avenue
Waltham, MA 02451 USA

Object of the declaration: NC-stat DPNCheck

Catalog Number: NC-030, NC-DP1, NC-DP2

Under the sole responsibility of NeuroMetrix, Inc., the object(s) of the declaration described above is in conformity with the requirements of the following documents:

Medical Device Directive 93/42/EEC:
Annex II – NC-030
Annex VII – NC-DP1, NC-DP2

European Authorized Representative:

EMERGO Europe
Molenstraat 15
2513 BH, The Hague
The Netherlands

Notified Body:
(Annex II Products Only)
TüV SüD Product Service GmbH
Notified Body Number 0123
Zertifizierstelle
Ridlerstasse 65
80339 Munchen
Germany

Date of First CE Marking: September 1, 2011 (NC-030, NC-DP1), September 11, 2012 (NC-DP2)

Signed for and on behalf of NeuroMetrix, Inc.



Rainer Maas
Director of QA/RA/Compliance
Waltham, MA 02451 USA

Appendix H: ELECTROMAGNETIC COMPATIBILITY DECLARATION

| NC-stat DPNCheck is intended for use in the electromagnetic environment specified below. The user should ensure that it is used in such an environment. | | |
|---|---------------------------|---|
| Emissions test | Compliance | Electromagnetic environment – guidance |
| RF emissions; CISPR 11 | Group 1 | NC-stat DPNCheck uses RF energy only for its internal function. Its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. |
| RF emissions; CISPR 11 | Class B | NC-stat DPNCheck is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes. |
| Electrostatic Discharge Immunity (ESD); IEC 61000-4-2 | ±6kV contact; ±8kV air | Floors should be wood, concrete or ceramic tile. |
| Radiated RF; IEC 61000-4-3 | 3 V/m; 80 MHz to 2.5 GHz | 3 V/m compliance level |
| Magnetic Fields; IEC61000-4-8 | 3 A/m | 3 A/m compliance level |