DPNCheck®

User Manual

(Model: NC-040)

Table of Contents

CHAPTER 1: INTRODUCTION

1.1 Indications For Use

The DPNCheck® is intended to measure neuromuscular signals that are useful in diagnosing and evaluating systemic and entrapment neuropathies.

1.2 Contraindications

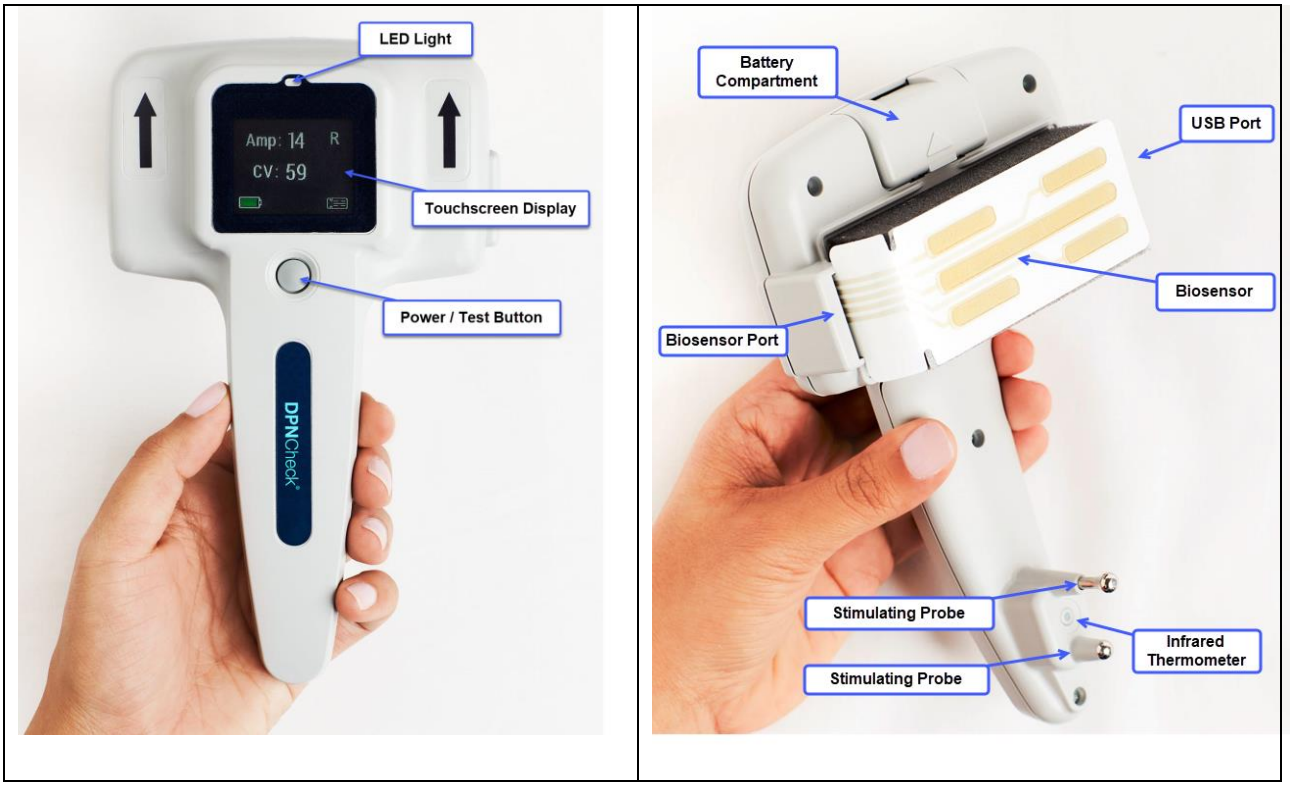
None.

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 the instructions for use (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
- Operation in close proximity to a shortwave or microwave therapy equipment may produce instability.

1.4 Device Overview

The 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.
- **Touchscreen Display** – area selecting and displaying test information and results.
- **LED Light** – status indicator.
- **Battery Compartment** – holds 3V Lithium battery (Panasonic model CR123A).
- **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 (DPNCheck model NC-DP2).
- **USB-C Port** – for communication with a PC (optional).

CHAPTER 2: SETUP

2.1 Package Contents

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

STANDARD COMPONENTS:

- DPNCheck device, model NC-040
- 3V Lithium Battery (Panasonic model CR123A)
- USB C Cable

Your device serial number can be found on the inside of the battery compartment, or from the Device Information screen (see Section 3.4). Your model number (MN) can be found on the information label on your device.

2.2 Reporting Damage

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

Phone: 844.DPN.CHECK (844.376.2432)
E-mail: customerservice@dpncheck.com

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

2.3 Battery Installation

The DPNCheck device uses a standard 3V Lithium-Ion Battery (Panasonic type CR123A).

1. Remove the battery compartment cover on the backside of the device (refer to picture on page 4 for the location of the battery compartment).
2. Insert the battery. Check the battery symbol inside the device to ensure proper orientation of positive and negative contacts.
3. Replace the cover.

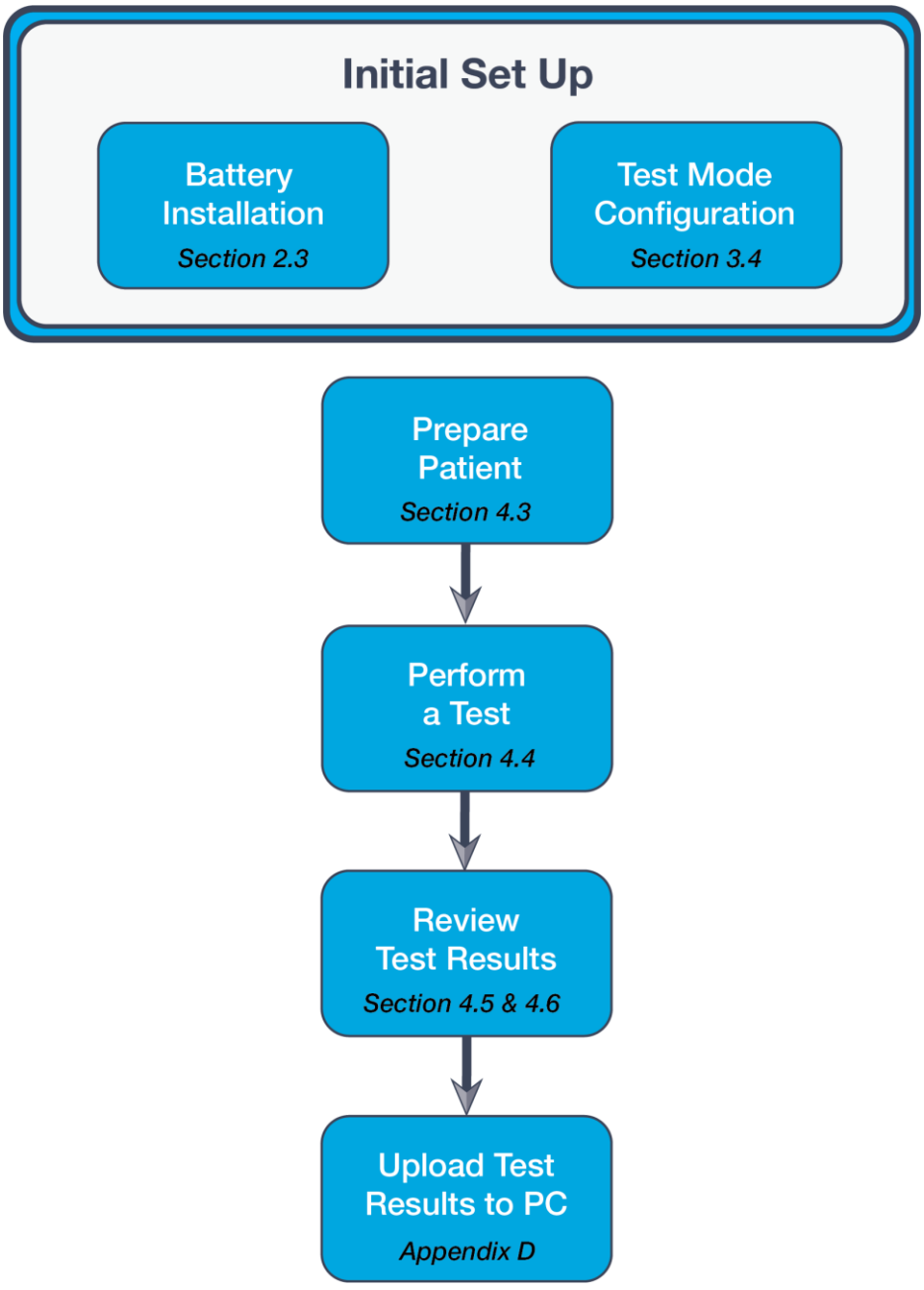
Make sure batteries are in good condition before using (i.e., no damage to outer case). When storing the DPNCheck device for an extended period of time, the battery should be removed prior to storing.

CHAPTER 3: DPNCheck OPERATIONS OVERVIEW AND CONFIGURATION

This chapter provides an overview of DPNCheck device operations. To prepare the device for patient testing, install the correct type of battery into the device (see Section 2.3) and set up the desired Test Mode (see Section 3.4).

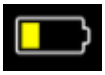
3.1 DPNCheck Operation Overview

The flowchart below illustrates the basic steps for preparing a DPNCheck device and using the device to perform a test (including an optional step of uploading test results to a compatible PC application).



3.2 Battery Status

The DPNCheck is powered by a replaceable 3V Lithium-Ion battery (Panasonic model CR123A). Battery status is indicated by a battery icon on the lower left corner of the display screen. The following icons provide information on the battery status:

	Battery is sufficient for testing.
	Battery is sufficient for testing but is low and will need to be replaced soon.
	There is not sufficient battery charge to complete a test.

See Section 2.3 for battery installation.

3.3 Biosensor Connection Status

To perform a DPNCheck test, a biosensor must be connected to the device. On the lower right corner of the display screen, a biosensor icon provides an indication on whether a biosensor is connected to the device. The following icons provide information on the biosensor connection status:

	No biosensor is connected.
	Biosensor is connected to the device.

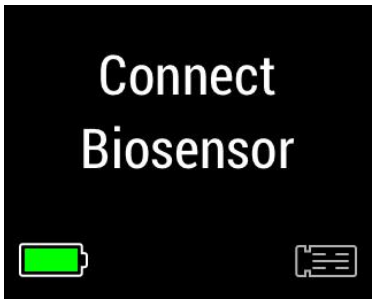
3.4 Test Mode Configuration and Device Information

The DPNCheck device can be configured for either Unilateral Mode or Bilateral Mode.

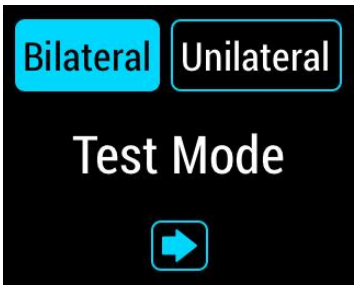
Unilateral Mode:
The device assumes the user is typically testing a single limb on each patient. Only one test can be stored on the device at a time.

Bilateral Mode:
The device assumes the user is typically testing both limbs and will store two tests, one for each limb.

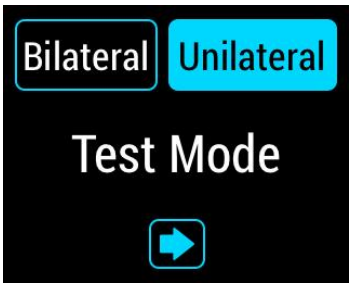
To set the Test Mode, power on device, *ensure no biosensor is connected* (see sample screen below, the biosensor icon on the bottom right corner shows outline only):



Then press and hold the Power/Test button for at least 5 seconds until the following Test Mode screen is shown. Select the desired test mode by tapping “Bilateral” or “Unilateral” button on the screen.

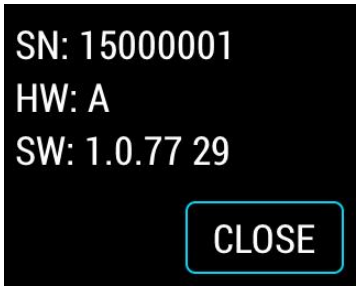


Bilateral Test Mode Selected



Unilateral Test Mode Selected

Once mode is selected, press the → to advance to the following Device Information screen:



The above sample Device Information screen is for illustration only. The actual display content on your DPNCheck device may be different. The screen displays the following:

- Device Serial Number (SN): 15000001 (also viewable from the inside of the device battery compartment)
- Hardware Version (HW) (example: A)
- Software Version (FW) (example 1.0.77.29)

Press CLOSE icon to exit this screen and return to Home screen.

CHAPTER 4: OPERATING INSTRUCTIONS

This chapter explains the basic operation of the DPNCheck device.

4.1 Power On

To power on the device, press the button under the Display Screen (refer to picture on page 4 for button location).

4.2 Power Off

The device will power off automatically after 1-2 minutes of inactivity.

Note: The last test is saved on the device until a new test is performed or until test is uploaded to the Reporter PC application. Contact DPNCheck Customer Service to obtain a copy of the Reporter application.

4.3 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 A). 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 B); prone with feet hanging off the exam table (Figure C); and chair with one leg resting on a chair (Figure D). 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.

Figure A: Preferred Position; side

Figure B: Alternative Position; side

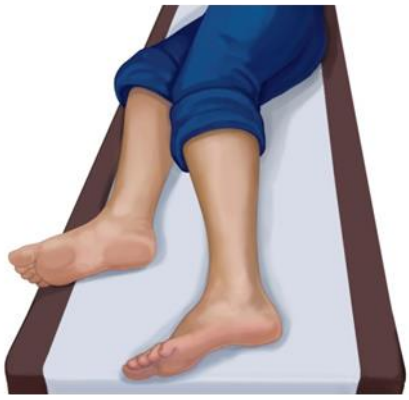
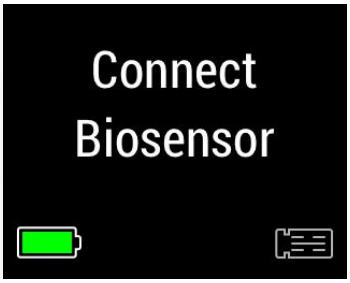


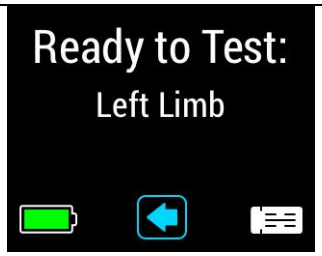
Figure C: Alternative Position; prone

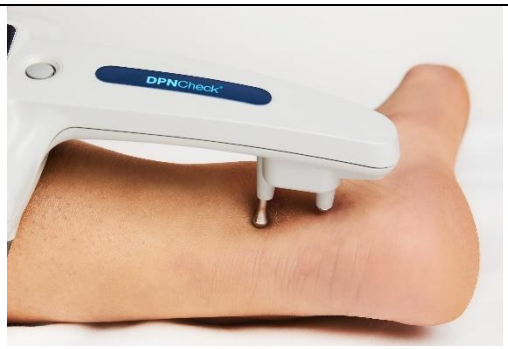
Figure D: Alternative Position; Chair -- leg up

4.4 Test Procedure

Proper patient positioning, skin preparation, and device placement are essential to accurately administer the test. The section below will demonstrate proper testing technique (refer to the DPNCheck Reference Guide for detailed testing instruction and troubleshooting).

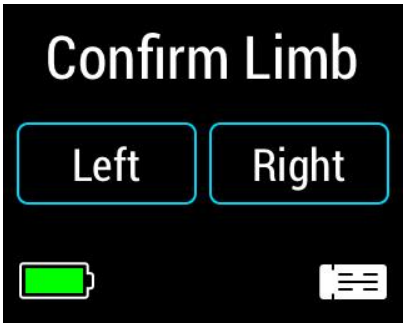
Step 1: Position the patient so that the outer ankle and calf can be easily accessed then vigorously scrub the testing area with the prep pad (provided with the biosensors).	
Step 2: Power on the device by pressing the power button. The display will prompt the user to Connect Biosensor.	 
Step 3: Fully insert the biosensor into the port. When inserted properly as shown, the narrow tail of the biosensor will be fully inside the port.	
Step 4: If you have not already done so, remove the protective liner from the foam and set aside for later use in protecting the foam adhesive between tests. Align the biosensor to the foam (provided with the biosensors).	

Step 5 (Bilateral Mode Only): The display will prompt user to select patient. Press either Same to continue testing the same patient or New to start testing a new patient.	
Step 6: The display will prompt user to select limb. Select the leg to be tested on the touch screen.	
Step 7: The display will then show Ready to Test screen with the selection made, and the green LED will illuminate. The blue left arrow allows you to return to the previous screen if needed.	 Ready to Test screen (Bilateral Mode)  Ready to Test screen (Unilateral Mode)
Step 8: Apply a small amount of Signa conductive gel (provided with biosensors) to each probe. The head of the probe should be covered with gel.	

Step 9: Remove the backing from the biosensor.	
Step 10: Locate the patient's outer ankle bone and Achilles tendon. The long probe should be placed behind the ankle bone, half way between the bone and the Achilles tendon.	
Step 11: Align the device on the lower calf by pushing down firmly on the foam. The arrow closest to the midline of the calf should point to the back of the knee. When the arrow is pointing properly, the inner edge of the biosensor will then sit adjacent to the midline (Achilles tendon). Ensure that the entire biosensor and both probes are making full contact with the patient's skin.	
Step 12: Press the button to start the test. The display will show "Testing". During the test the LED blinks green when each stimulus is delivered. Maintain firm pressure on both the biosensor and the probes throughout the test. Test times may vary per patient but normally lasts for 10-15 seconds.	

How to Stop the Test: Anytime during the test, you can lift the device from the patient to stop the test. An error will be displayed if you halt the test prior to completion.	
Step 13: Once results are displayed the test is complete and the device may be removed from the leg.	

Note: If, at the end of a test, the DPNCheck suspects that the limb may have been misidentified, the user will be prompted to confirm the limb before the results are displayed.



If the user confirms that the correct limb was originally specified, then the test results are displayed. If the user selects the limb that is not consistent with the limb specified at the start of the test, the test will result in a Limb Not Confirmed error.

How to Stop the Test: Anytime during the test, you can lift the device from the patient to stop the test.

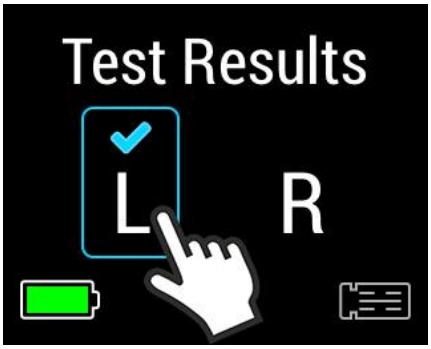
See Appendix F for troubleshooting.

4.5 Test Results Review – Single Limb Results

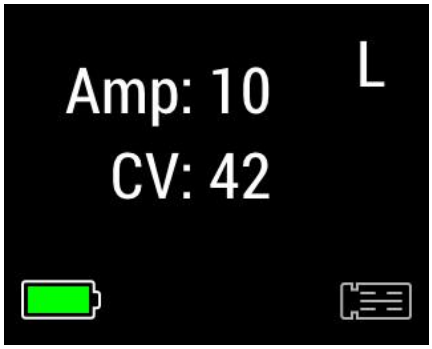
When the test is complete, the device will display the sural nerve conduction amplitude (Amp) in microvolts (µV) and the conduction velocity (CV) in meters per second (m/s). In cases where the patient has low amplitude (between 0-4 µV) and the CV cannot reliably be reported, only the amplitude will display on the device.

Disconnect the biosensor to review test results if the results are no longer shown on the screen.

The screen below indicates that valid test results are available for Left limb. Press the limb indicator (e.g., L) to review the test results for that limb:

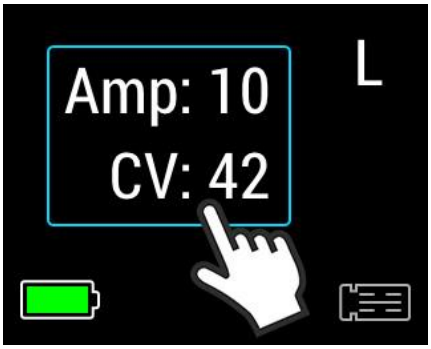


Press the limb indicator to review the test results →



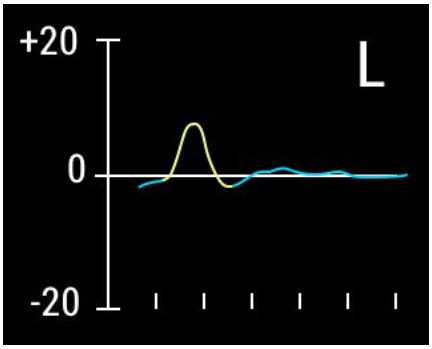
If both limbs have a check mark above them, it indicates that results are available for both limbs (Bilateral Mode only). Please refer to Section 4.6 for instructions on how to switch results between two limbs.

To view the waveform for the test, press the area where the Amp and CV results are displayed. When you touch that area, it will highlight with a blue outline. Once you remove your finger from the screen, the waveform display will appear:



Numerical results for left limb

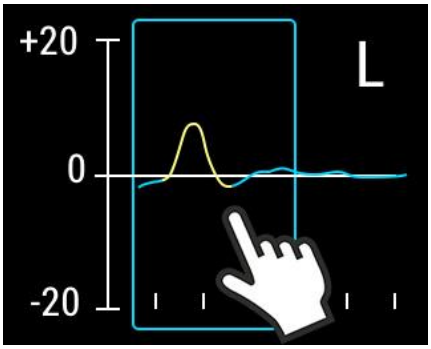
Press the area where the Amp/CV results are displayed to switch to waveform screen →



Waveform display for left limb

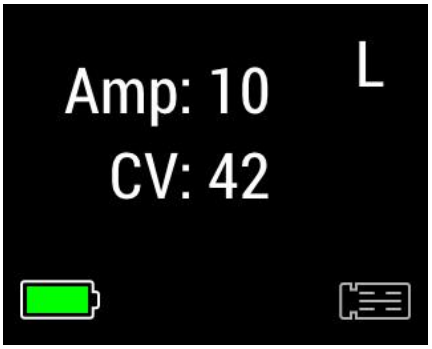
When the waveform screen is first displayed, the waveform is displayed at a fixed -20µV to +20µV scale. See Section 4.7 for instructions on how to change the waveform display scale.

To toggle back to the numerical results screen, press the waveform area and it will highlight with a blue outline as seen below:



Waveform display for left limb

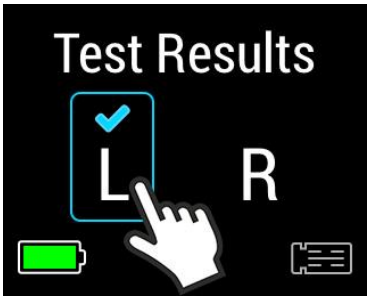
Press the waveform area to switch to the Amp/CV result screen →



Numerical results for left limb

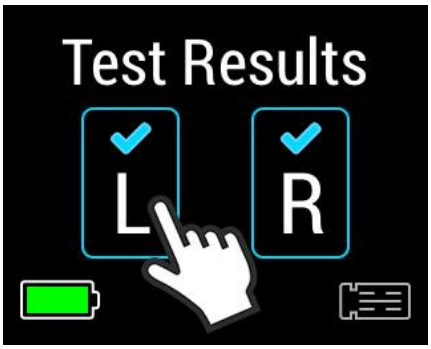
In certain cases, a test may only show an Amplitude result on numerical screen as seen below:

Following a test, once the device has powered off and been turned back on or the button has been pressed, the device will display the following indicating that there are results stored for the limb indicated. Make sure that the biosensor is **NOT** connected in order to view Test Results screen.

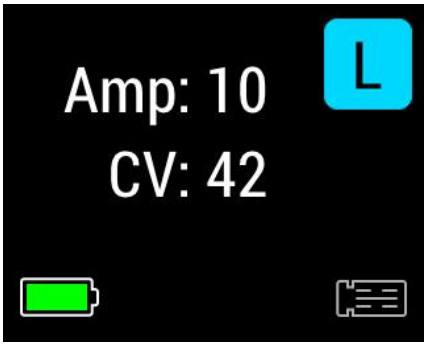


4.6 Test Results Review – Results Available for Both Limbs

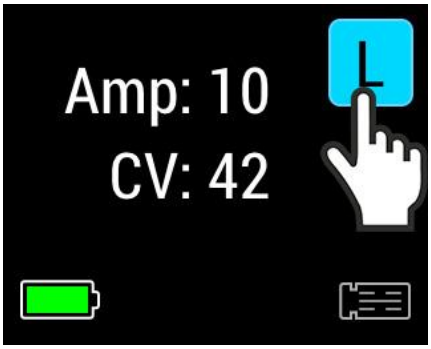
When the device is configured to Bilateral Test Mode (see Section 3.4 on how to select Test Mode between unilateral and bilateral), results may be available for both left and right limbs of the same patient. The screen below indicates that valid test results are available for both limbs. Press the limb indicator (e.g., L) to review the test results.



Press one limb indicator (L or R) to review the test results for that limb →

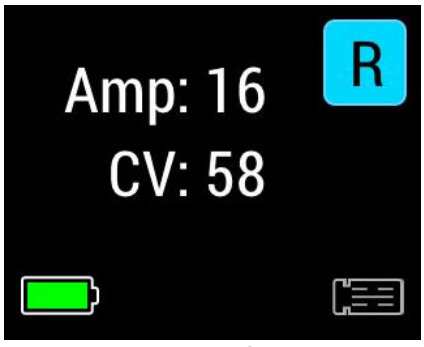


The limb L inside a filled blue square indicates that test results for the other limb are available. To view the results of the other limb, simply press the filled blue square.



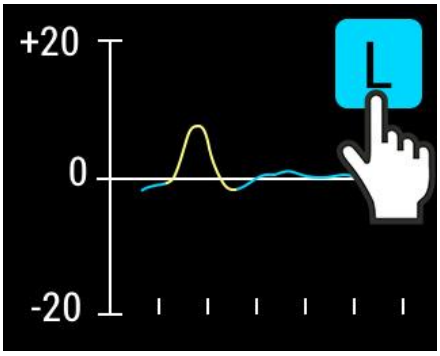
Numerical results for left limb

Press the filled blue square to view the test results of the other limb →



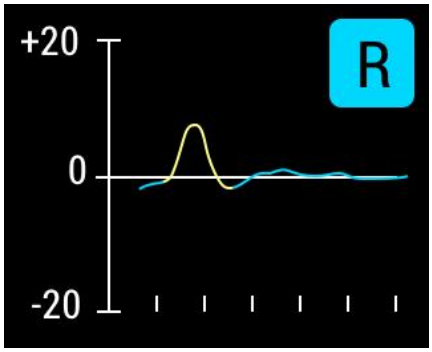
Numerical results for right limb

When the waveform for a limb is displayed, if the upper right corner limb indicator is inside a filled blue square, the waveform for the other limb can be viewed by pressing the blue square once.



Waveform display for left limb

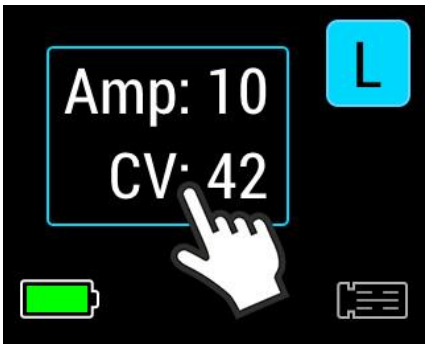
Press the filled blue square to view waveform of the other limb →



Waveform display for right limb

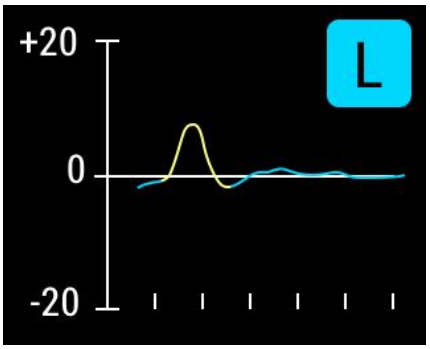
When the waveform screen is first displayed, the waveform is displayed at a fixed -20µV to +20µV scale. See Section 4.7 for instructions on how to change the waveform display scale.

To view the waveform of the same limb from the numerical result screen, press the area where the Amp and CV results are displayed. When you touch that area, it will highlight with a blue outline. Once you remove your finger from the screen, the waveform display will appear:



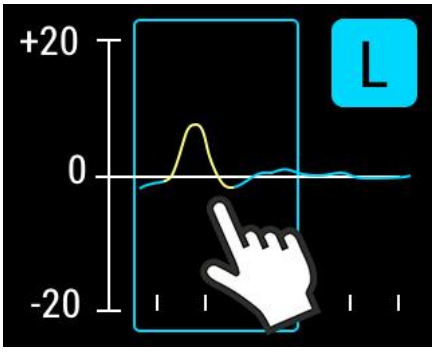
Numerical results for left limb

Press the area where the Amp/CV results are displayed to switch to waveform screen →



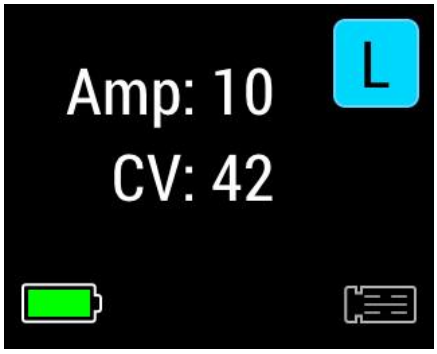
Waveform display for left limb

To toggle back to the numerical results screen, press the waveform area and it will highlight with a blue outline as seen below:



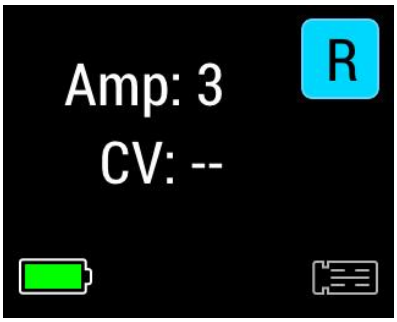
Waveform display for left limb

Press the waveform area to switch to the Amp/CV result screen →

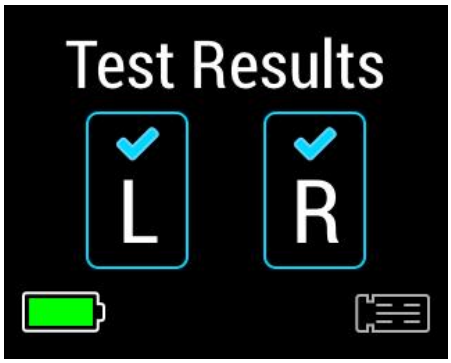


Numerical results for left limb

In certain cases, a test may only show an Amplitude result on the numerical result screen as seen below.



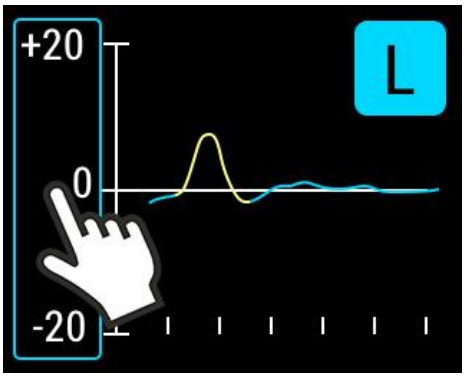
Following a test and disconnecting the biosensor, once the device has powered off and been turned back on or the button has been pressed, the device will display the following indicating that there are results stored for the limb indicated. Make sure that the biosensor is **NOT** connected in order to view Test Results screen.

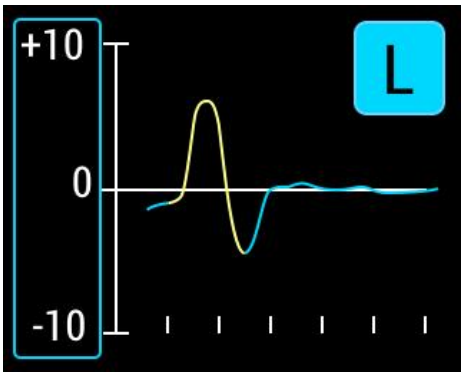


4.7 Waveform Scaling

When the Waveforms screen is first displayed, the waveform will be scaled to a fixed Y-axis of -20µV to +20µV.

To change the scale, press the left side (scale) area of the screen and the waveform will toggle to an auto-scale view.





4.8 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.

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

- Please see Appendix F for likely reasons if a test error occurs.

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 ≤4 µV
- 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 DPNCheck device should only be used with DPNCheck single patient use biosensors. Repeat use of the same biosensor on multiple patients will disable the device as indicated by the "Device Locked" error screen. Disabled devices must be returned to DPNCheck for a factory reset. **Customers will be required to pay a service fee and all shipping and handling charges.**

CHAPTER 5: SAFETY, WARRANTY SERVICE, CARE, AND SERVICE

5.1 Safety Notes

Do not immerse any portion of the 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.

The DPNCheck device should only be used with DPNCheck biosensors.

The DPNCheck device should only be placed over the intended anatomy as described in this manual.

User should ensure no excess gel on the skin during testing.

Do not use any biosensor that has missing gel pads.

In order to use DPNCheck, the patient's leg must be large enough for the device to contact the proper anatomy, i.e. both stimulators must be able to contact the outer ankle and detector biosensor must be able to contact the calf.

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 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.

5.2 Maintenance and Cleaning

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

The 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 and disinfecting the device and 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 cloth with water to clean the exterior of the unit. Isopropyl alcohol applied to a soft cloth may be used for disinfecting the exterior of the unit.
- It is recommended that the stimulating probes be cleaned following testing to remove the gel.
- Do not use abrasive cleaners or strong solvents to clean the device.
- If the foam pad becomes dirty or contaminated by bodily fluids, it should be replaced.

5.3 Disposal of Device, Batteries, and Biosensors

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

After use, biosensors may be disposed of in normal trash receptacles.

5.4 Storage of Biosensors

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.

5.5 DPNCheck Limited One Year Warranty

DPNCheck manufactures its hardware products from new components in accordance with industry standard practices. DPNCheck warrants the 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 DPNCheck 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 DPNCheck.

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 DPNCheck device through authorized DPNCheck service centers.

DPNCheck will repair or replace products covered under this limited warranty that are returned to DPNCheck facility or an authorized DPNCheck representative. To request warranty service, you must call the DPNCheck Customer Service at 844.DPN.CHECK (844.376.2432) or call an authorized technical support representative within the warranty period. DPNCheck will issue a Return Material Authorization (RMA) Number. The product must be shipped to DPNCheck in the original or equivalent packaging,

with prepaid shipping charges, and insured against loss or damage during shipment. DPNCheck 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 DPNCheck. If DPNCheck repairs or replaces a product, the original warranty is not extended.

DPNCHECK MAKES NO EXPRESS WARRANTIES OR CONDITIONS BEYOND THOSE STATED IN THIS WARRANTY STATEMENT. DPNCHECK 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.

DPNCHECK 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.

DPNCHECK 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 DPNCheck limited one-year warranty only.

5.6 Service

Should the DPNCheck device require service, contact DPNCheck Customer Service at 844.DPN.CHECK (844.376.2432). When you call DPNCheck to request service, please be prepared to provide the following information:

- Serial number (serial number can be found inside the battery compartment or on Device Information screen)
- Description of the problem

Devices outside of their warranty are subject to a service fee for repairs.

Do not return any component of the 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 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.

5.7 FDA Notification

The 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 DPNCheck, 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, DPNCheck should be notified of any device failures or malfunctions. Issues encountered should be reported to DPNCheck Customer Service. Outside of the United States, problems should be reported to the nearest DPNCheck device distributor. This information will help ensure that DPNCheck 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	226 g

Environmental Shipping, Storage, and Operating	
Temperature	-20 °C to 50 °C
Humidity	10% to 90%, non-condensing
Altitude	55 kPa to 100 kPa
Operating	15 °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)	410V +/-10%
Stimulator Max Current	70 mA +/-10% (at max patient impedance of 5.7 Kohm)
Stimulator Pulse Width	100 µs +/-5 us
Stimulation Frequency	1 Hz (maximum)
Skin Temperature Measurement	Non-contact, infrared, +/- 1°C
Battery	3.0 V Lithium Primary (Panasonic CR123A)
Display	Resistive touchscreen display
Water Resistance	IEC 529 IP20 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

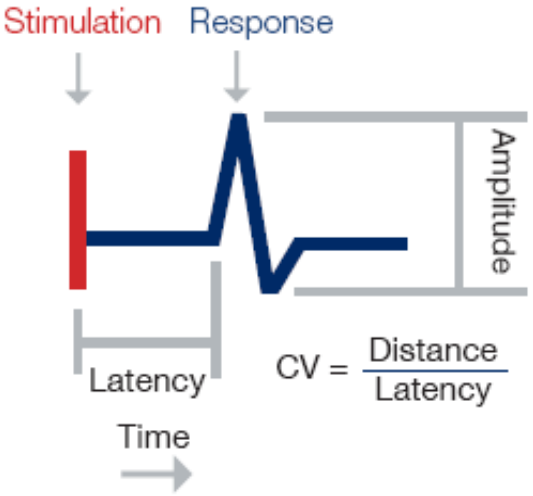
APPENDIX B: SYMBOLS

	Consult Accompanying Documents
	Type BF Applied Part
	WEEE (Waste Electronic and Electrical Equipment) symbol in accordance with council directive 2002/96/EC
MN	Abbreviation for model number
	Indicates the acceptable upper and lower limits of relative humidity for transport and storage.
	Indicates the acceptable upper and lower limits of atmospheric pressure for transport and storage.
	Indicates the maximum and minimum temperature limits at which the item shall be stored, transported or used.
	Fragile, handle with care
	Indicates that the transport package shall be kept away from rain and in dry conditions
	Do not re-use
	Use by Date
	ISO Symbol 7000-3082 for “Manufacturer” Manufacturer: The Electrode Store (TES) 159 W Mason Ave Buckley WA 98321

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



	CV	Amplitude
Axon Loss		↓
Axonal Atrophy	↓	↓
Demyelination	↓	

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 µV

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 µV

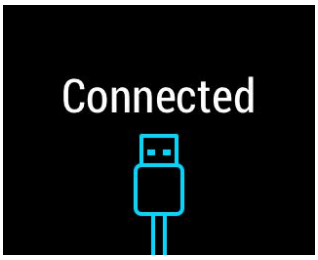
APPENDIX D: UPLOAD TEST RESULTS TO COMPUTER

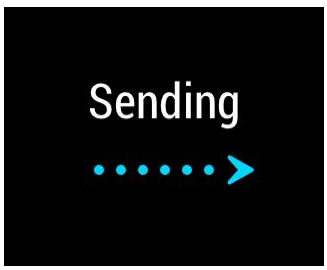
Uploading Data

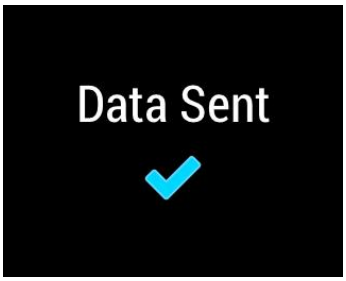
The most recent test results may be uploaded to the Reporter PC application (or to Communicator, see compatibility note below) using a USB cable. A USB-C port is located on the side of the device. Note: If the device powers off before performing an upload, the data is still saved on the device and may be uploaded.

1. Power on the device.
2. Connect the USB cable to the device and PC.
3. Ensure that the Reporter application is open on the PC (please refer to the end of this section on how to obtain a copy of the Reporter application). The Reporter application must be open for data to transfer. If the device is connected and powered on but Reporter is not open, the following message will display:

4. After connecting the device to the PC with the USB cable, the device will display the following screen sequence:







Note: “Data Sent” screen is only shown when used with the Reporter application.

Application Compatibility Note: DPNCheck model NC-040 is compatible with the Communicator application, but it is recommended that it be used with the Reporter application. Please note that if using DPNCheck in Bilateral Mode with Communicator, only the most recent test will be uploaded if bilateral tests are saved in memory. If using DPNCheck with Communicator the “Data Sent” screen will not display following upload.

Obtain a Copy of the Reporter Application:

Please contact DPNCheck Customer Service on how to obtain a copy of the Reporter Application:

Phone: 844.DPN.CHECK (844.376.2432)
E-mail: customerservice@dpncheck.com

International customers should contact the nearest authorized DPNCheck representative.

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 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 between the stimulating probes.

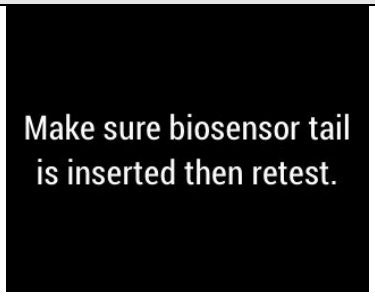
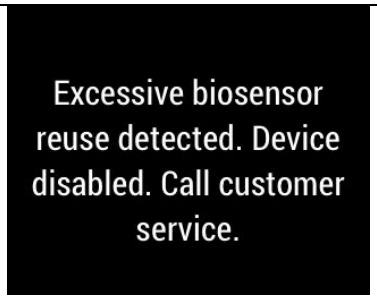
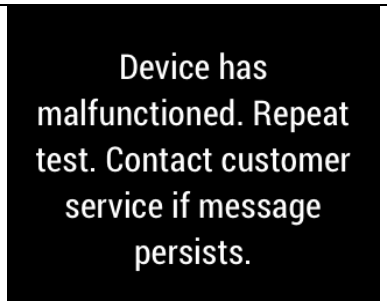
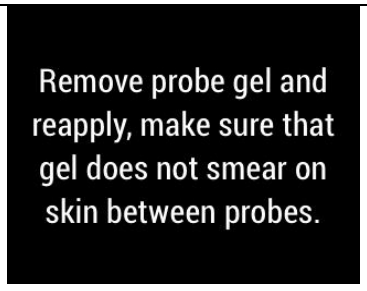
If the temperature is below 23 °C, then the patient is too cold to reliably measure nerve conduction and the test will stop with the following message displayed:

It is recommended in this case to warm the patient's ankle to at least 24 °C before repeating the test.

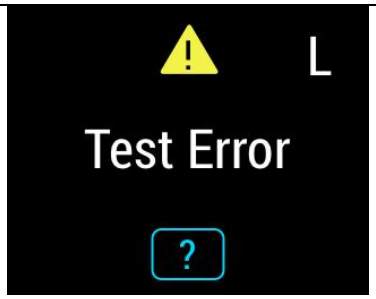
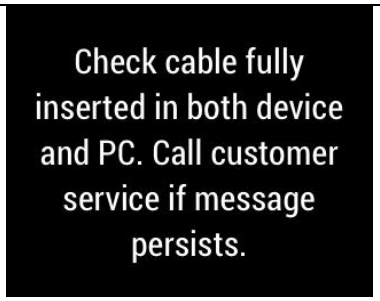
Note: If there is noticeable damage to the infrared lens (located between the stimulating probes), the device should be repaired or replaced.

APPENDIX F: TROUBLESHOOTING

When an error message is displayed with a  symbol, pressing the screen will then display additional information regarding the error message.

LED Status	Error Message	Help Screen (accessed by pressing the ? on the Error Message screen)
		
●		
●		
		

		Check biosensor liner removed, patient leg and foot are relaxed. If message persists, reposition patient.
		Repeat test with correct limb selected.
		Warm patient's ankle to at least 24C/75F before repeating test. Tester should keep hand away from probes.
		Reapply probe gel, allowing time for gel to absorb into the skin. Use consistent probe pressure during test.
		Check biosensor liner removed. Repeat skin preparation, apply consistent pressure to device during test.

LED Status	Error Message	Help Screen (accessed by pressing the ? on the Error Message screen)
		
		
		
		

APPENDIX G: ELECTROMAGNETIC COMPATIBILITY DECLARATION

The 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	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 A	The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocation or re-orienting the equipment.
Electrostatic Discharge Immunity (ESD); IEC 61000-4-2	±8kV contact; ±16kV air	Floors should be wood, concrete or ceramic tile.
Radiated RF; IEC 61000-4-3	10 V/m; 80 MHz to 2.5 GHz	10 V/m compliance level
Magnetic Fields; IEC61000-4-8	3 A/m	3 A/m compliance level