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CHAPTER ONE: NC-stat DPNCheck Communicator Overview

1.1 Glossary of Terms

Archive

Noun. Refers to the location where all patient studies are stored after being reviewed and interpreted.

Verb. Refers to the action by the user which moves any study in the Queue to Archive.

Datastore

Noun. Refers to location in which patient studies are saved by the software.

Communicator

Noun. Application to tag NC-stat DPNCheck tests with patient information, edit waveform cursors and generate reports.

Test

Noun. Refers to a single patient test that has been imported into the software.

Study (or Studies)

Noun. Refers to a single patient study which may include one or more patient tests. Studies is also a search function available in the main menu bar.

PC (or Personal Computer)

Noun. Refers to computer that operates on a Microsoft operating system.

Queue

Noun. Refers to where patient tests first appear when imported into the software.

Retention

Noun. Refers to a time period in which backup files are kept within the system.

Waveforms

Noun. Refers to the shape and form of an electrical signal. Sensory Nerve Action Potential (SNAP) is what the NC-stat DPNCheck device measures and displays for each patient test imported into the software.

1.2 Communicator Operation

The Communicator software for the NC-stat DPNCheck device allows you to store and print reports of the patient data collected using the device. With this software, you can:

- Store NC-stat DPNCheck data and print patient reports
- Review the physiologic signals recorded by the device
- Add patient information and physician interpretation to the report
- Store data locally on your computer
- Print data sheets to provide patients with results and specific instructions
- Export reports directly to EMR systems
- Export study data to spreadsheets or other databases

CHAPTER TWO: Communicator Installation

2.1 PC Requirements

The following information outlines the equipment users must have before the Communicator software can be installed. For more information, please contact Customer Service at 1.888.786.7287.

An existing Microsoft PC can be used to install the Communicator software. Apple® Mac® computers are not compatible with the NC-stat DPNCheck device or software. Any PCs to be purchased should exceed the recommended specification to gain the longest lifespan from the new PC.

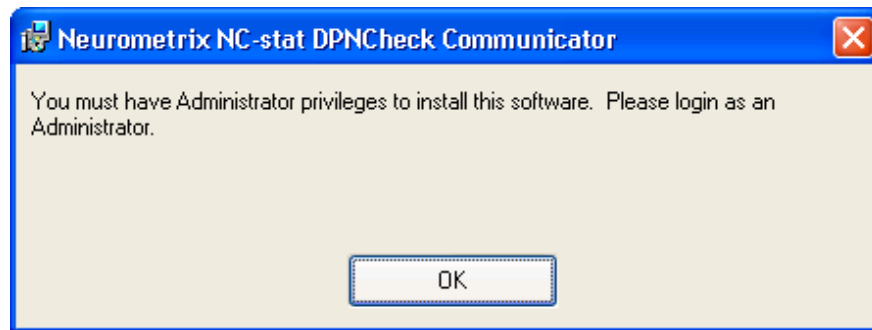
Processor	Pentium®-compatible 400MHz or higher.
RAM	256MB. Lower specifications may be used, but with reduced performance and reliability.
Monitor	CRT or flat panel. Contrast ratio and screen resolution can vary. Settings should be optimized by the user to ensure proper evaluation of data waveforms.
Hard Disk	50 MB of available hard disk space. Lower specifications may be used, but with reduced performance and reliability.
Operating System	Windows XP with Service Pack 3 (32-bit), Windows Vista (32-bit), Windows 7 (32 and 64-bit)

Printers

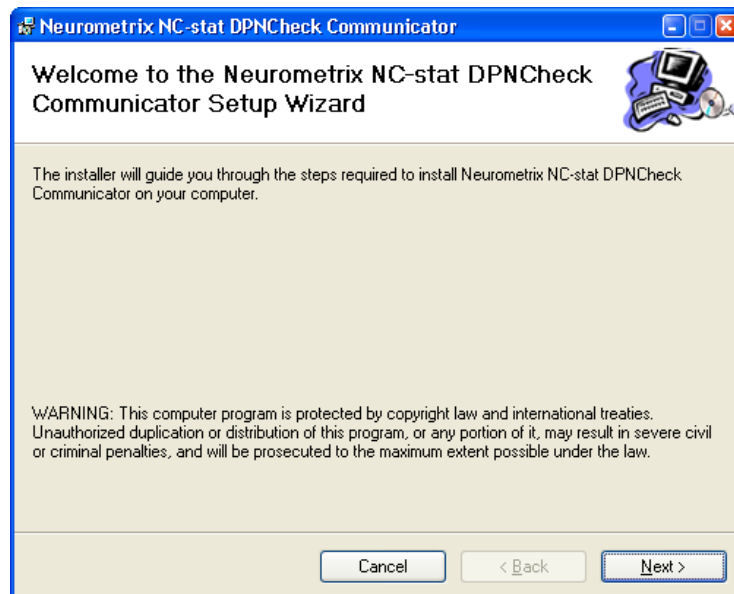
Installation of a printer is the responsibility of the user. NeuroMetrix does not provide printer support and cannot guarantee any minimum performance level nor output quality from any standard printer due to the nature of the printing processes. We would initially recommend a high quality letter/A4 inkjet printer.

2.2 Installation Instructions

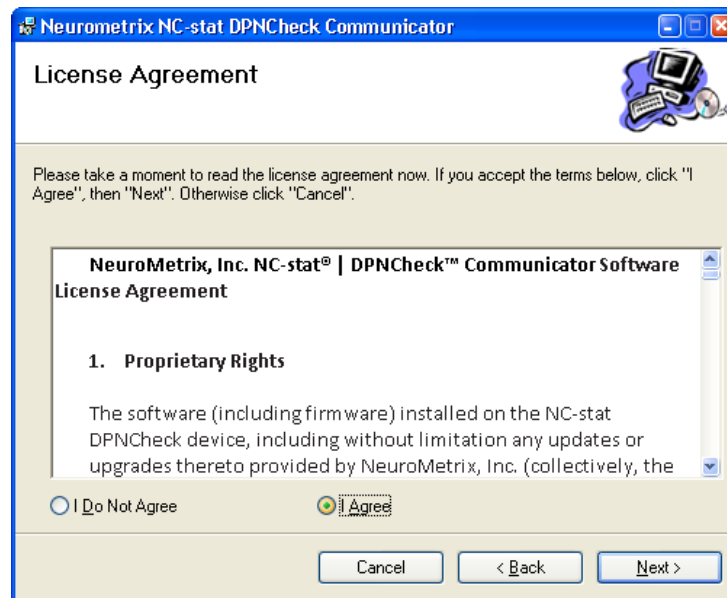
1. Load the Communicator Software CD into the PC disk drive.
2. Follow the prompts on screen. You must be logged in as the Administrator to properly download the software or this screen will appear:



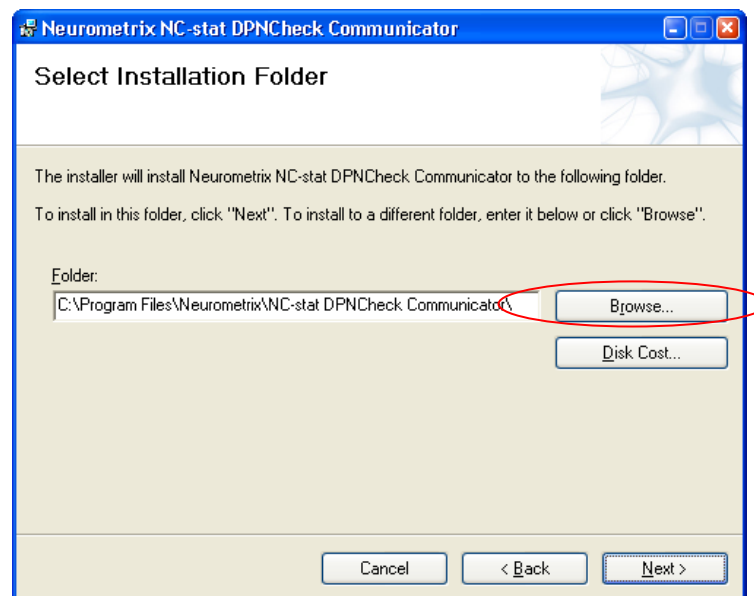
3. Once the Welcome Screen appears, select **Next**.



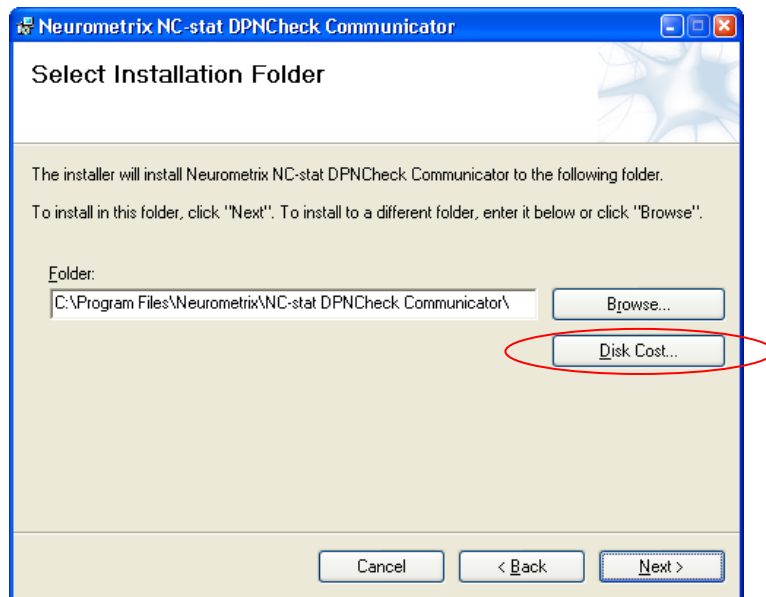
4. Review the NC-stat DPNCheck Communicator Software License Agreement, select **I Agree** then **Next**.



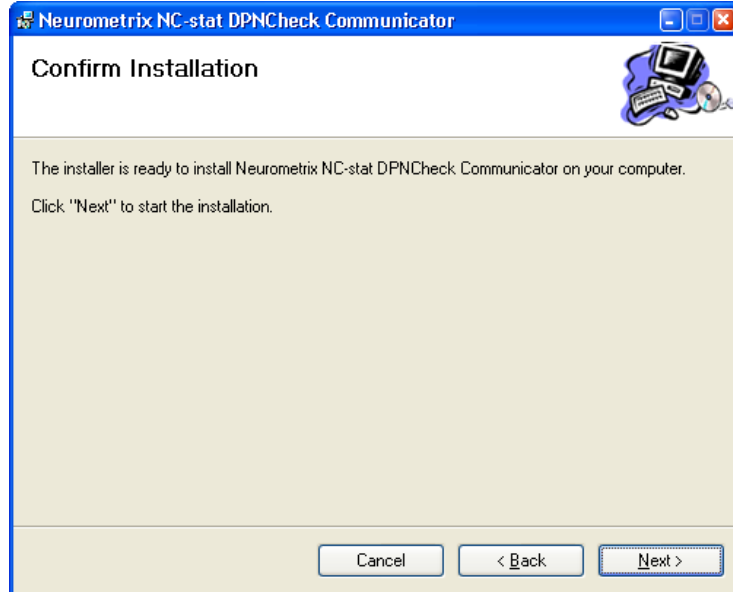
5. Select Installation Folder. The default creates a file on the C drive shown below. Select **Next**. If you would like to change the file location, select **Browse** to select the preferred location.



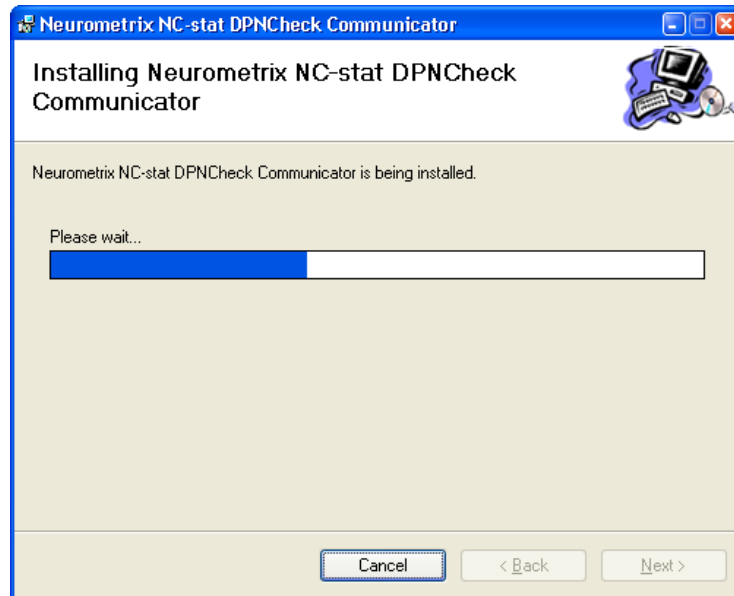
If the user would like to review the available disk space prior to installing the software, select **Disk Cost** and a screen will appear showing the available disk space shown below.



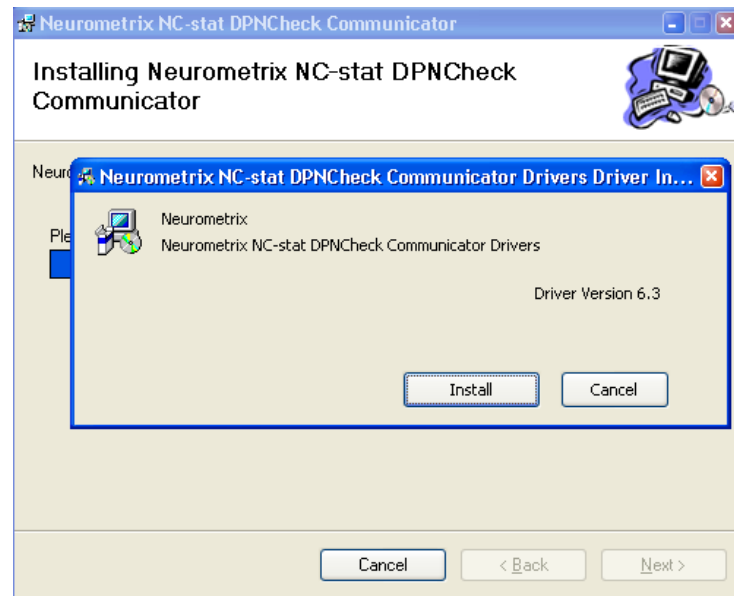
6. The software will now be ready to install on your computer. Select **NEXT**.



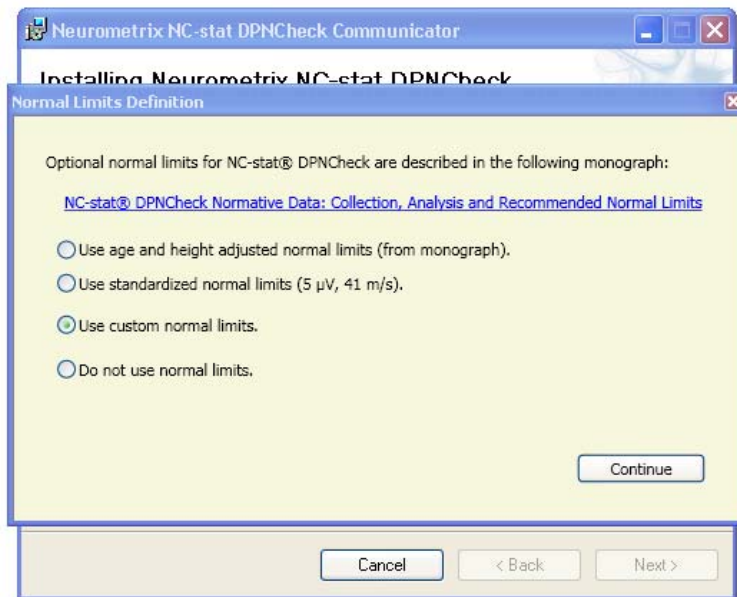
A progress screen will appear to update the status of the install.



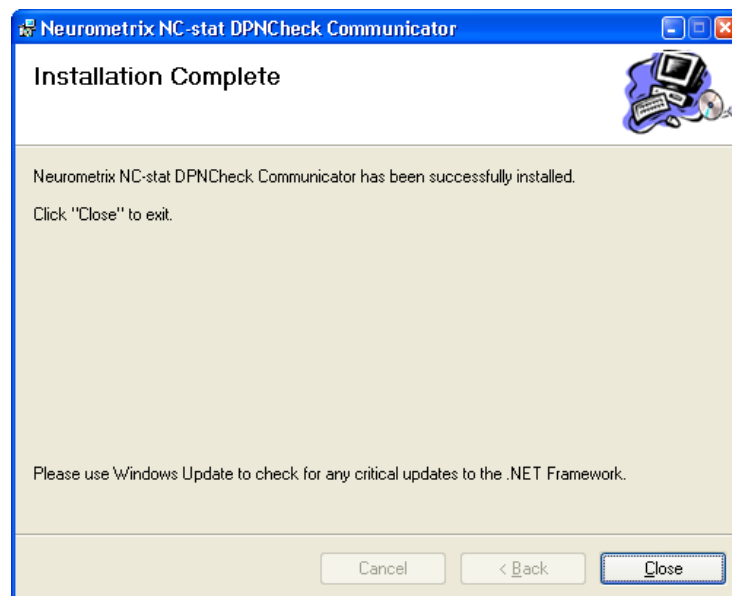
7. The Driver Install screen will appear. Select **Install**.



8. Choose whether you want to use normal limits described in the respective monographs then select **Continue**.

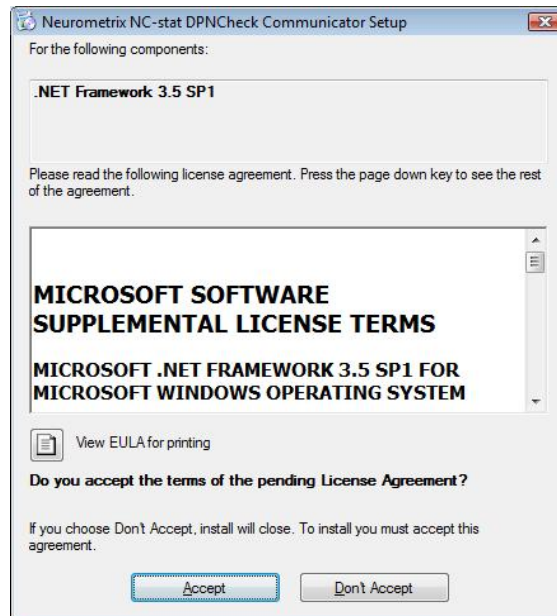


9. The Installation Complete screen will appear when done. Select **Close**. A shortcut icon will appear on the user's desktop.

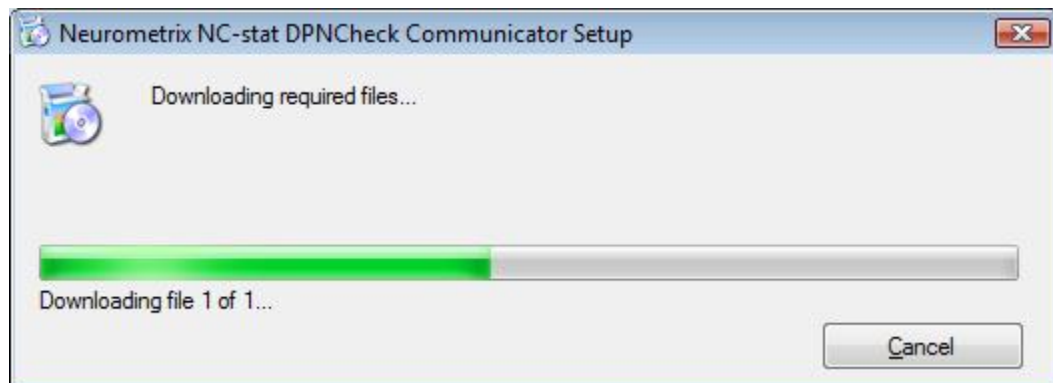


Note: If the computer does not have .NET 3.5 installed, please reference the following 3 steps to install the necessary Framework. You must be connected to the Internet to download this component from Microsoft.

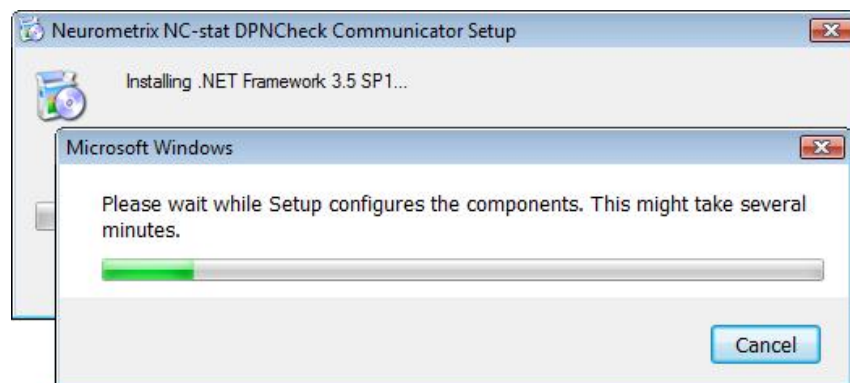
1. You will be prompted below that .NET 3.5 is not installed. Select click **Accept**.



2. Download the update:



3. The update will install automatically:



CHAPTER THREE: Using the Communicator

3.1 General Overview

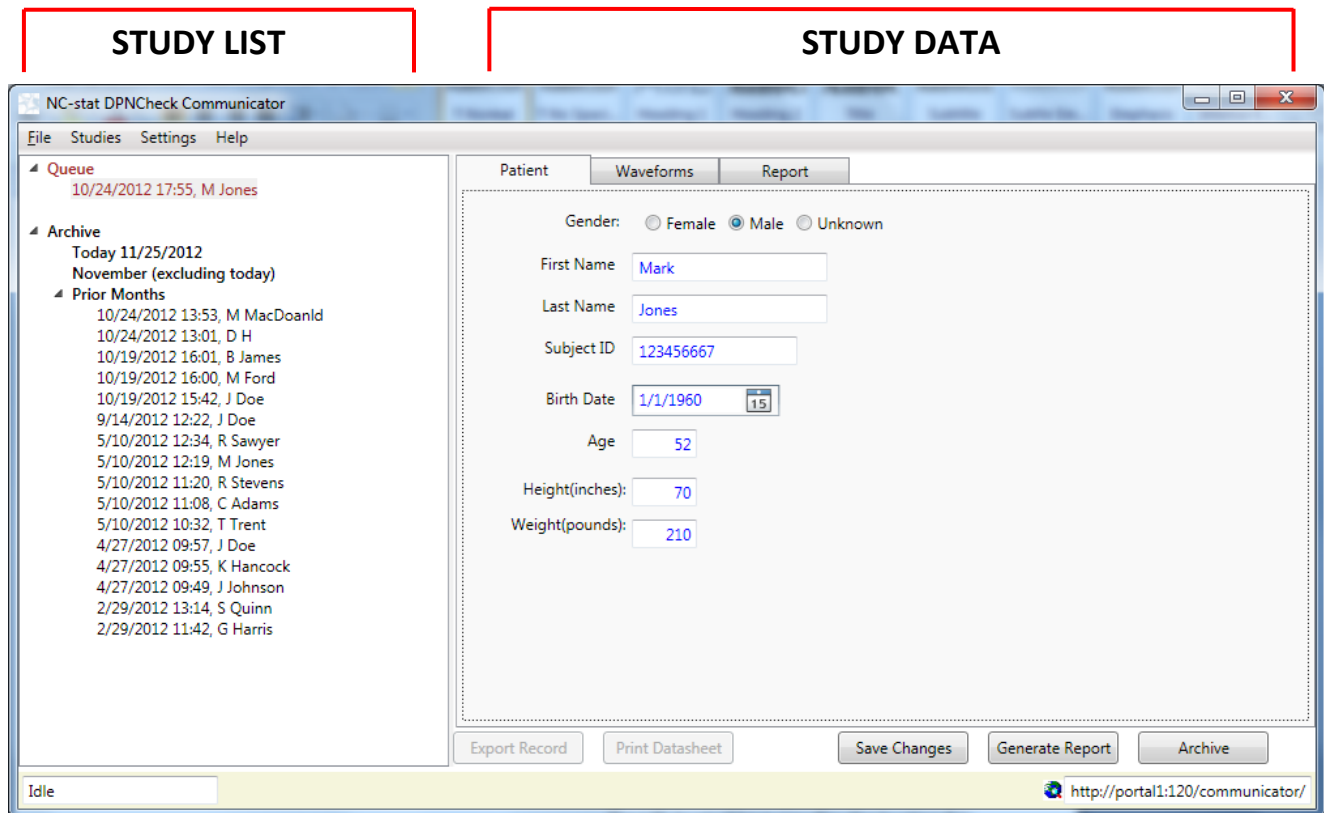
General use of the Communicator for data transfer, review, and report generation follows the following basic steps:

1. Perform a test on a patient.
2. Open Communicator software on the PC. The software must be running first before connecting the device to the PC.
3. Connect device to the PC with the USB cable provided with the device.
4. Data transfer takes a few seconds. Enter Patient ID and limb; data will appear in the Queue list.
5. If a second test is needed for the patient, disconnect USB, perform the test, and follow steps 1-4 again.
6. Review the patient data; enter any desired patient, practice, and interpretation information.
7. Send the study to the Archive list and Generate a Report.
8. Print a Datasheet for patients (optional).
9. Export report to EMR system (optional).

Note: The NC-stat DPNCheck device stores one test at a time. If you perform multiple tests for a single patient, transfer your data to Communicator after each test. At import, you are only asked to input the patient ID. All other information may be input at your convenience.

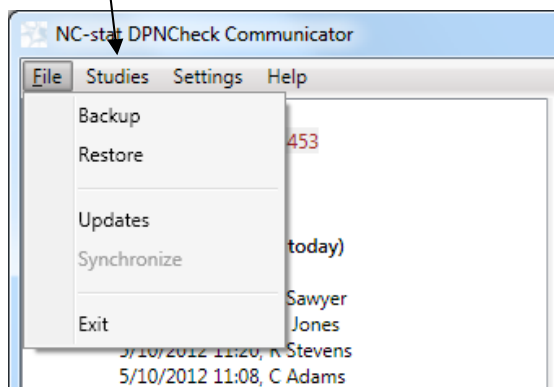
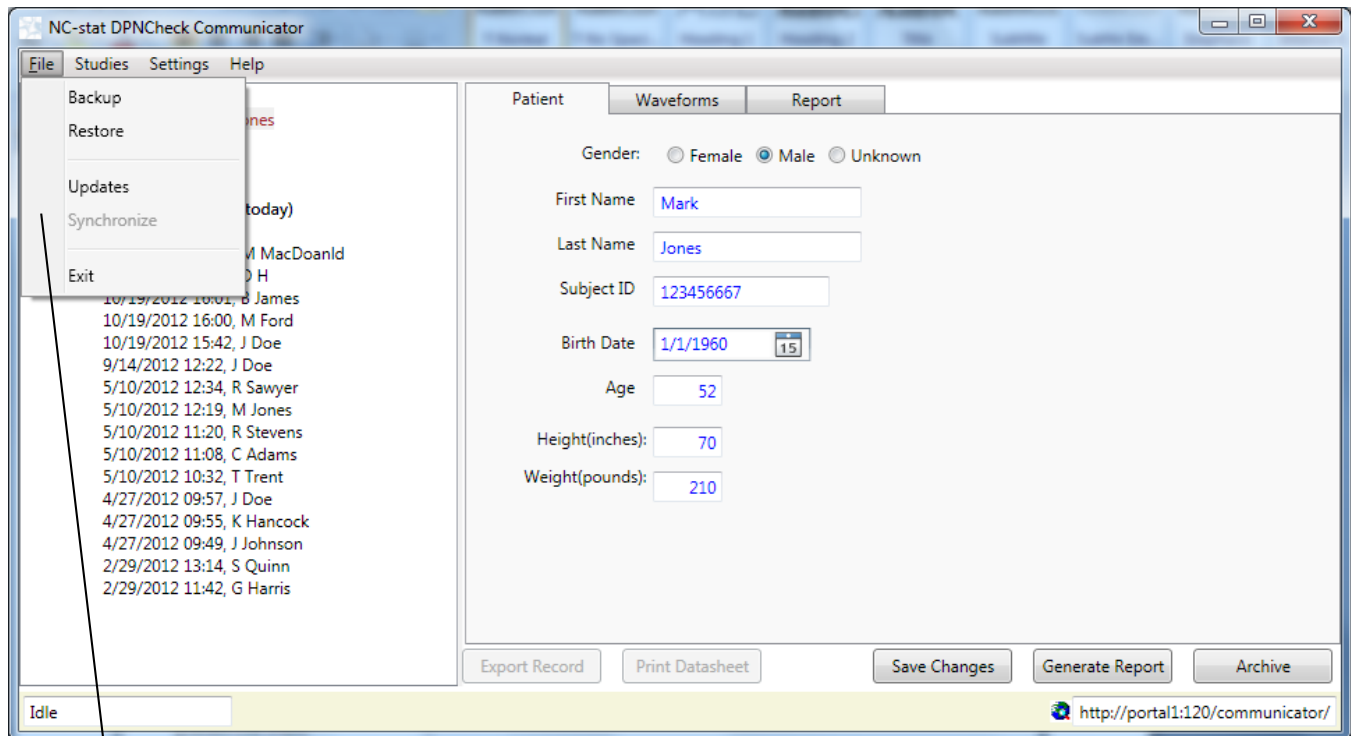
3.2 Screen & Menu Overview

The NC-stat DPNCheck Communicator software consists of a menu bar and two windows: the Study List (left) and Study Data (right).



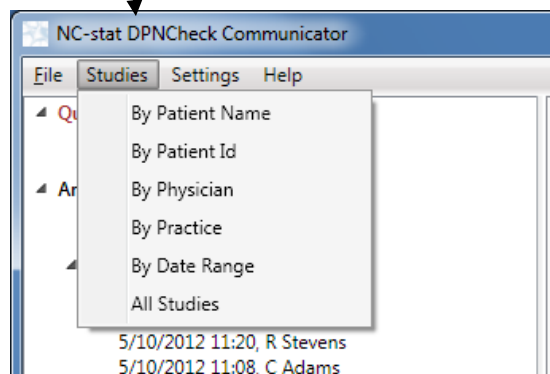
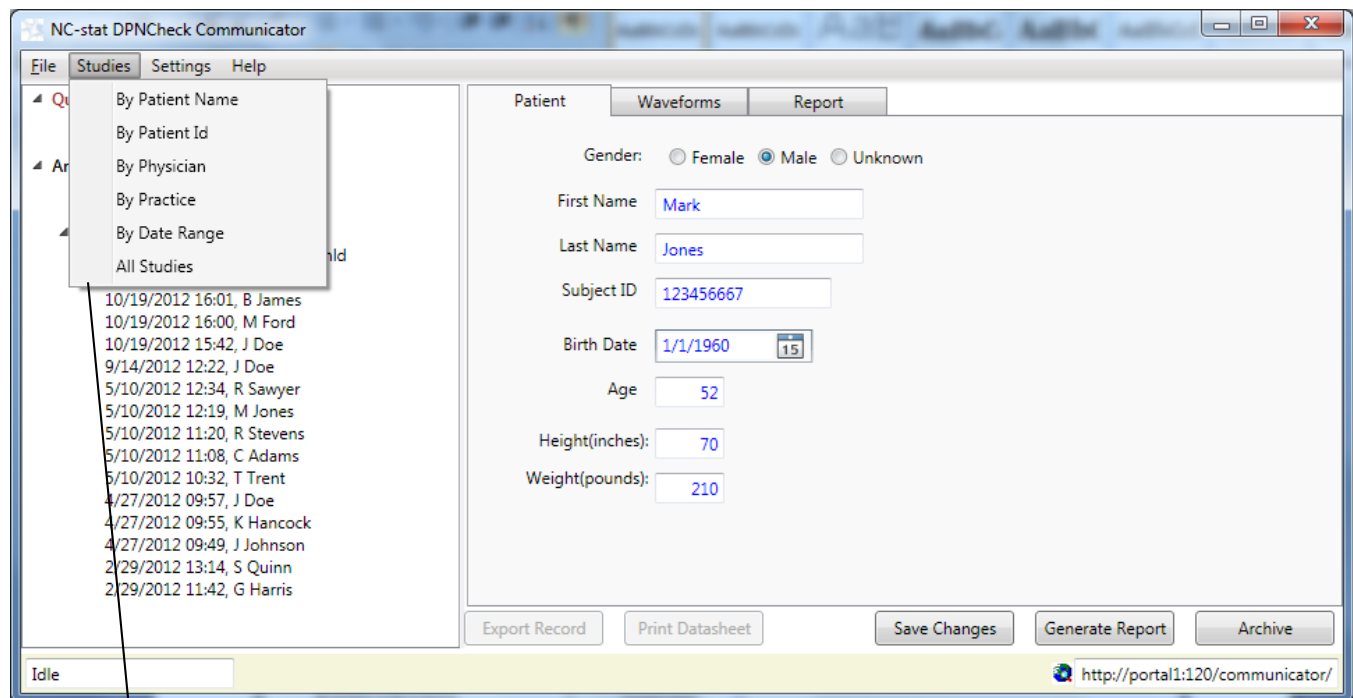
From the menus, you are able to change settings, search for studies, and perform other software operations. The Study List window on the left of the screen displays the list of NC-stat DPNCheck studies transferred to your PC and allows you to select a study to view. The Study Data window on the right side of the screen allows you to review data of the study selected from the Study List and add information to the report. The sections below provide further detail on the menu options and window displays.

File Menu



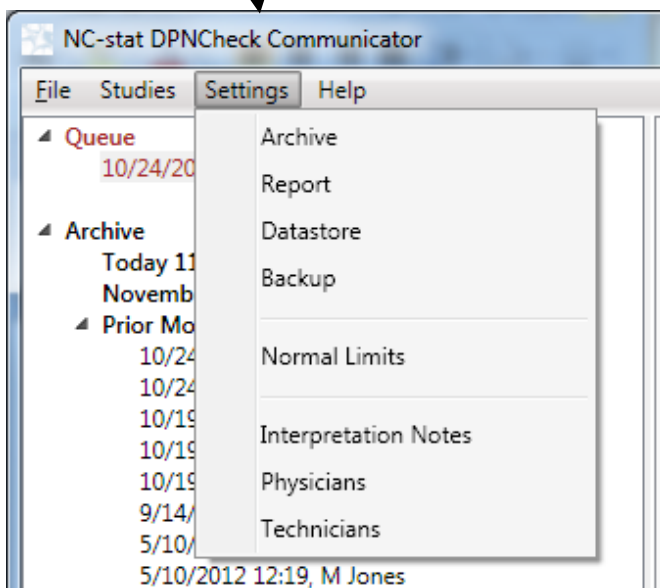
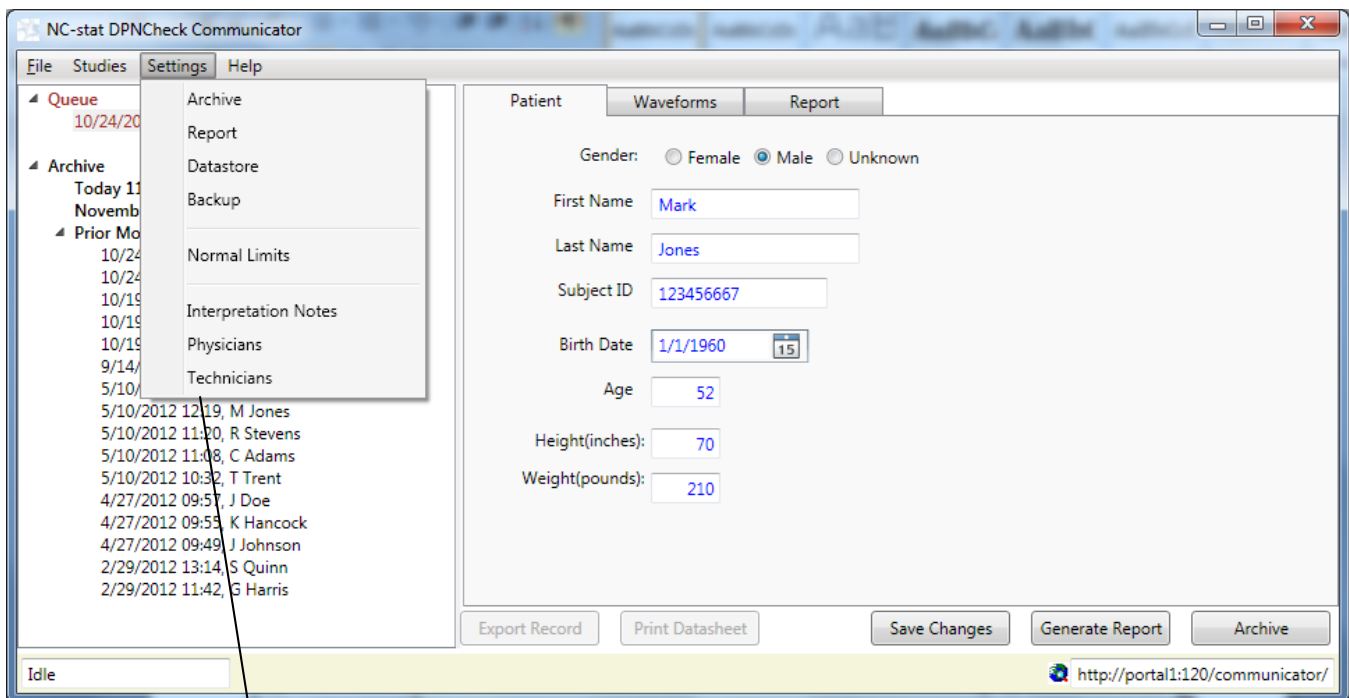
- **Backup** allows you to manually back up any data stored within the Communicator software file locations at any time. You may also set the software to perform automatic back-ups (see Settings section).
- **Restore** allows you to restore both the test data (Queue, Archive and Reports). Configuration settings (Archive, Datastore, Advanced, and Backup) can also be restored from the last backup taken. Note: If a new test is imported and Restore is selected, you will not lose a test that has been imported.
- **Updates** this function has been disabled.
- **Exit** allows you to terminate your current session and close the software.

Studies Menu

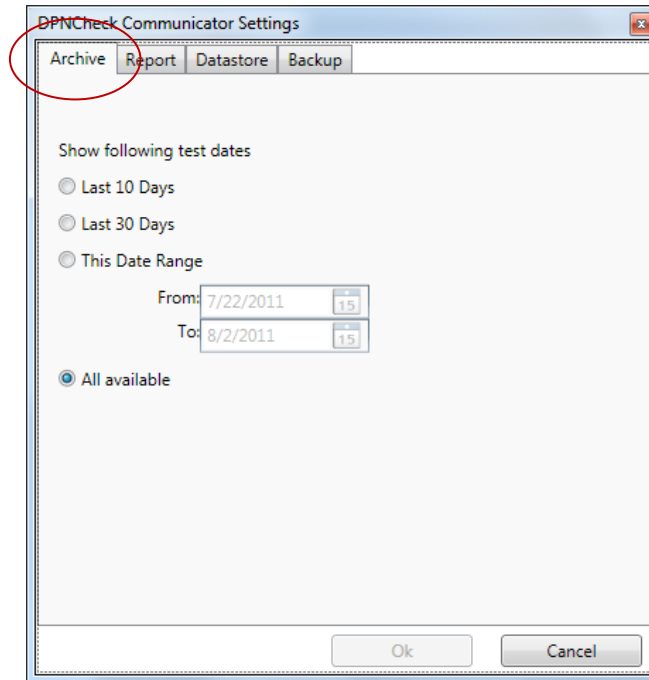


- **By Patient Name** allows you to review the studies by a patient's name (i.e. Smith, John).
- **By Patient ID** allows you to review the studies by a patient's ID number.
- **By Physician** allows you to review studies by physician name.
- **By Practice** allows you to review studies by practice name.
- **By Date Range** allows you to review studies within a specific date range.
- **All Studies** allows you to review a list of all studies.

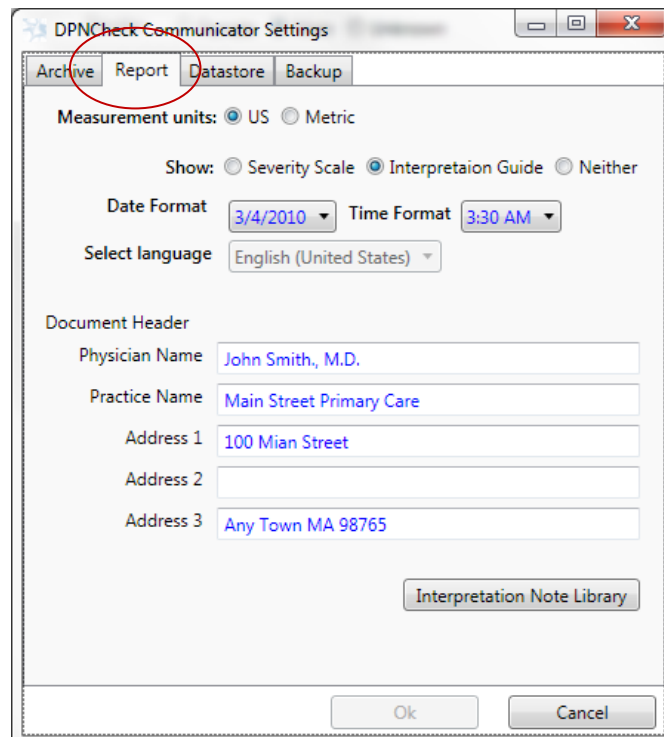
Settings Menu



- **Archive** allows you to modify the timeframe for tests that will display in the Archive list located on the left side of the screen. Users can select one of the following: Last 10 Days, Last 30 Days, Date Range, and All Available.



- **Report** allows you to customize the format for printed sural nerve conduction study reports. Users can select the date and time format and language. Users can select option to show the Severity Scale or the Interpretation Guide on the report. Also shows the default physician profile of the document header (e.g. clinician name, practice name, address) as shown in the sample below. Note: This information may also be entered or modified in the Report tab of a particular study.



Sample Report Header:

Sural Nerve Conduction Study

John Smith, M.D.
100 Any Street
Sometown, MA 98765

**Practice
Information**

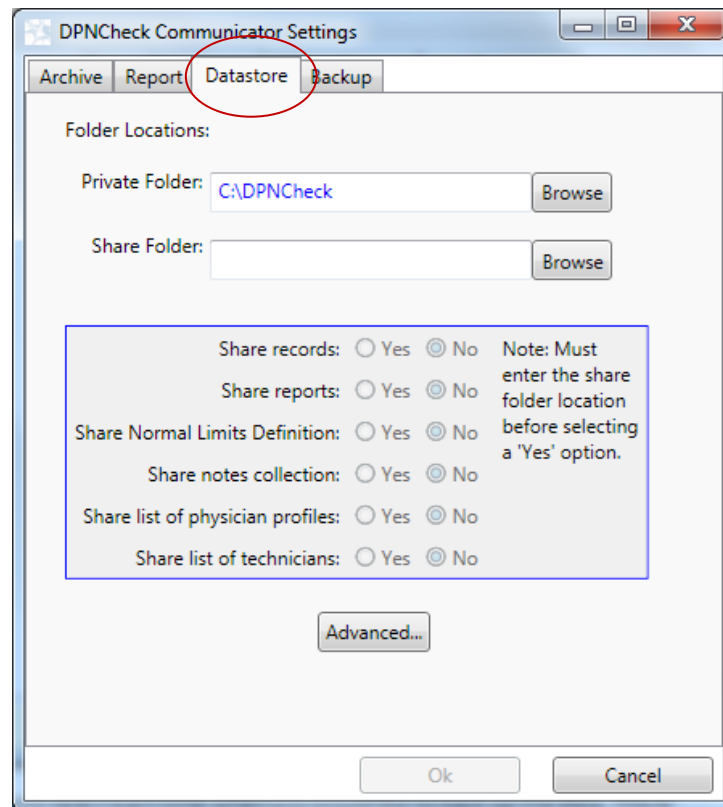
**Patient
Information**

Patient Name: Robert Crabtree
Patient ID: 0000028
Gender: Male
Birth Date: 06/20/1952

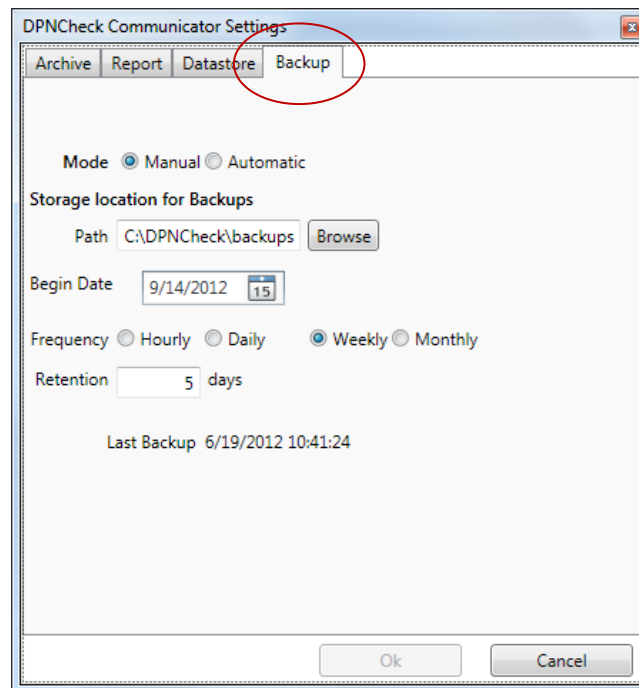
Test Date: 09/13/2011 08:51:52

Report also allows you to update or edit the Interpretation Note Library with patient notes that, when selected, will auto-populate on a patient report. See Section 3.4 for details on creating interpretation notes.

- **Datastore** allows you to locate or change where you save your files generated from the software on your local PC. Default locations are set by the software. A shared folder can also be assigned so that two or more computers and/or users on a network can share studies (records), reports, normal limit definitions, notes and profiles.

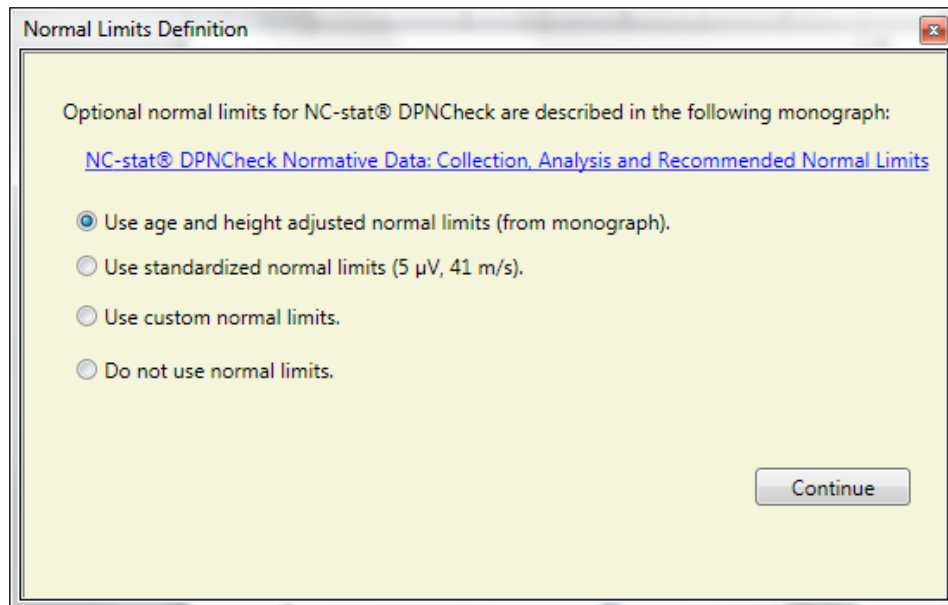


- **Backup** allows the user to set preferences for backing up data. The system default mode is a manual process which requires you to select each time when you would like to back up the data. This is completed by selecting **File** then **Backup**. In the backup settings menu, you can select an automatic backup which allows you to back up data based on scheduled time and frequency. The timing will be set based on the Begin Date that is selected. For example, if you select a frequency of Weekly and a Begin Date of December 5th which falls on a Monday, your system will backup once per week on every Monday until any settings are changed. The image below displays an example of these settings:

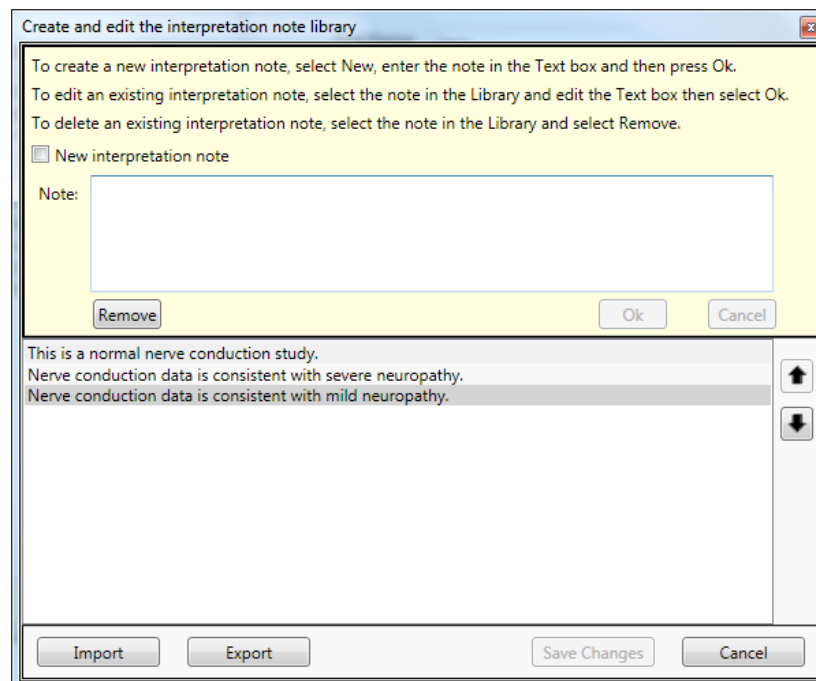


The retention period refers to the timeframe in which patient tests are stored within the Archive. The default setting is 5 days. For example, if you set a retention period of 5 days and you backup 5 times in one week and need to revert back to the date from the backup occurred on Day 3, this is possible based on the retention time period that is selected.

- **Normal Limits** allows users to select their preferred choice of normal limits for amplitude and conduction velocity. See Section 3.5 for details on defining normal limits.



- **Interpretation Notes** allows users to create and edit the Interpretation Note library. See Section 3.4 for details on creating interpretation notes.



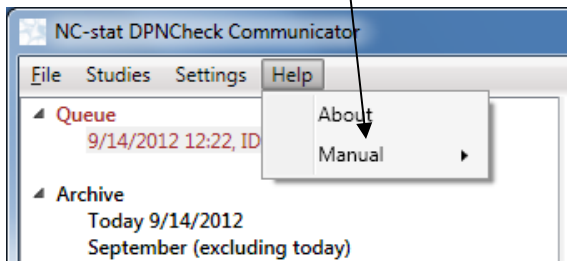
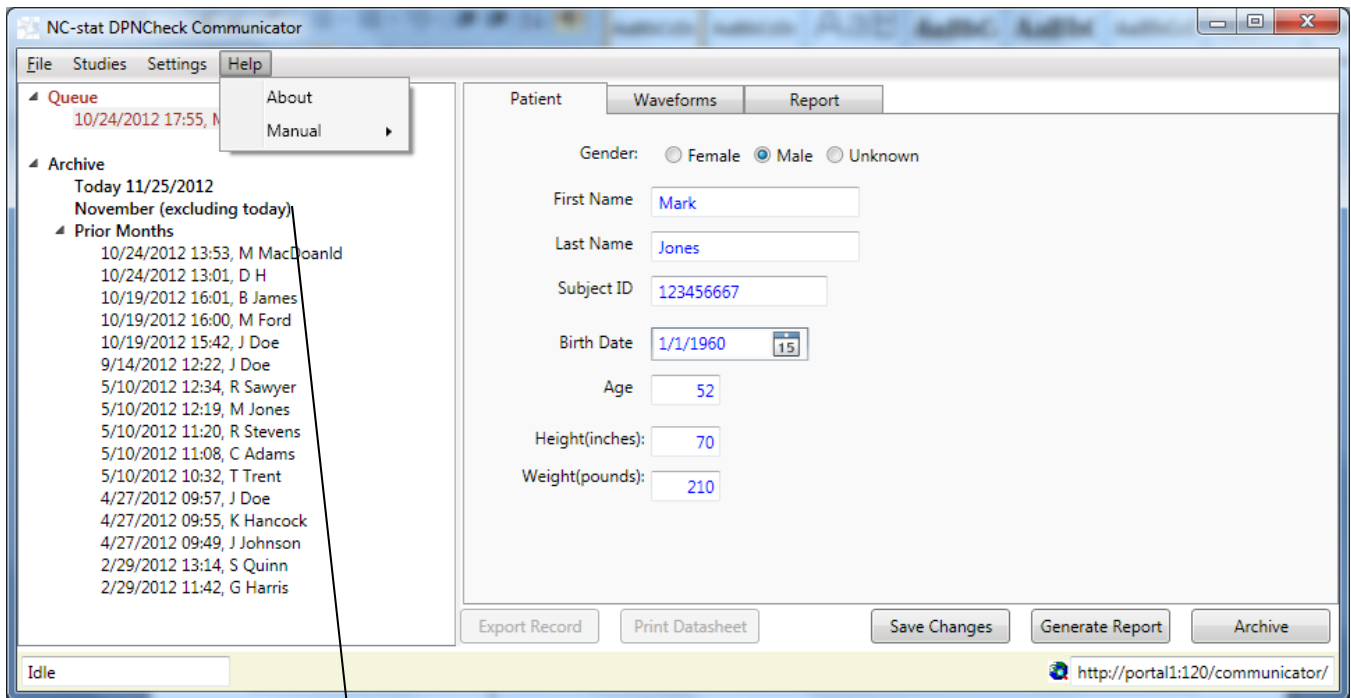
- **Physicians** allows you to create a library of physician profiles. A physician profile can then be selected within the Report tab for each study.

The dialog box is titled "Create and edit the list of physician profiles". It contains a list on the left with the text "Select a profile or 'enter new profile'", followed by "[enter new profile]", "John Smith, M.D.", and "Jane Washington, M.D.". To the right of the list are several input fields: "Physician Name" (with a "Delete" button), "Practice Name" (containing "Main Street Primary Care"), "Address 1" (containing "100 Main Street"), "Address 2" (containing "Suite A"), and "City, State Zip" (containing "Any Town, MA 98765"). There is a checkbox labeled "Default Profile" above the "Physician Name" field. At the bottom right are "Save Changes" and "Cancel" buttons.

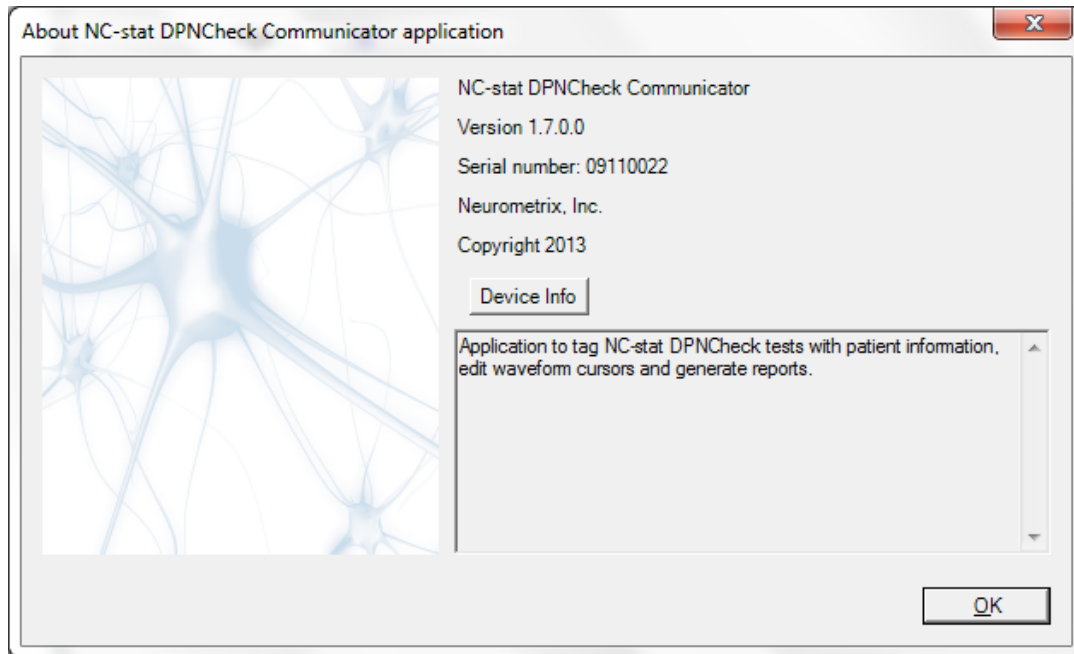
- **Technicians** allows you to create a library of technician profiles. A technician profile can then be selected within the Report tab for each study.

The dialog box is titled "Create and edit the list of technicians". It contains a list on the left with the text "Technicians", followed by "<add name>", "Anne Kelley", and "Tim Shaw". To the right of the list are a checkbox labeled "Default Technician" and a "Delete" button. At the bottom are "Save Changes" and "Cancel" buttons.

Help Menu



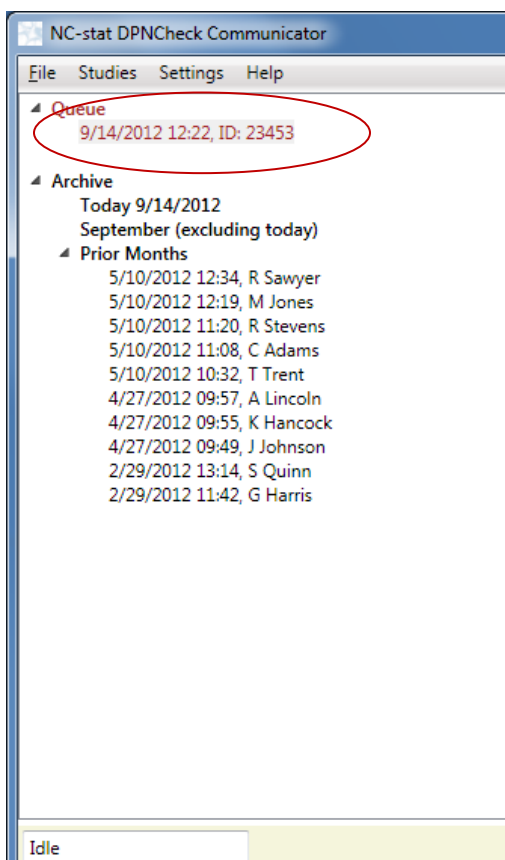
- **About** allows you to review information about the Communicator version number. To check the device revision number select **Device Info** on the About screen.



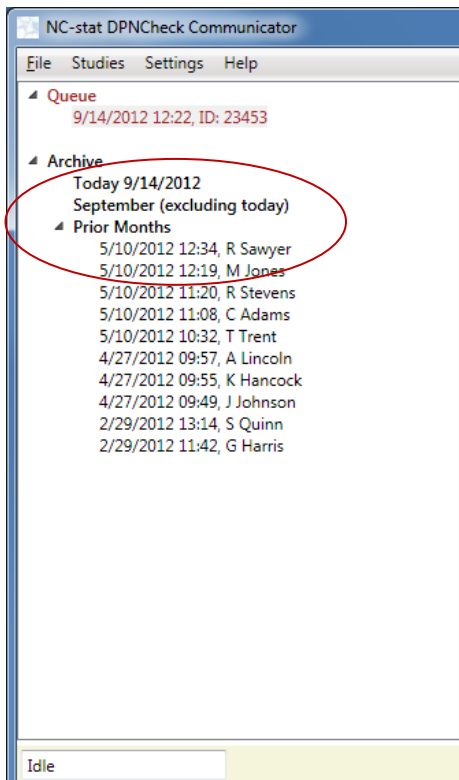
- **Manual** includes electronic files of both the NC-stat DPNCheck device and Communicator software manuals.

Studies List (Queue & Archive)

Studies List is located on the left side of the screen and is where patient tests are stored. **Queue** is the location where tests are imported from the device and assembled into a patient study that may contain one or more tests. If you would like to combine multiple tests from the same patient into a single study, the data must be imported from the NC-stat DPNCheck Device and attributed to the same patient ID. Note: Test data can be combined into one study that has been imported into the software within the previous 5 days. If data for the same patient ID is entered after the 5 day limit, a unique report will be created for the patient which is accessible under the **Studies** menu.



Tests are moved from the **Queue** to the **Archive** once they have been reviewed, interpreted and saved. This action is completed by selecting the **Archive** button located at the bottom right corner of the screen. You can set this window to display all studies or only recent studies (see section above on Settings Menu).



Data Tabs

Data Tabs are located on the right side of the screen and includes Patient, Waveforms, and Report tabs. From any of the three tabs, using the buttons along the bottom of the screen you may Save any changes you have made, Generate a Report, Print a Datasheet, Export a Record to an EMR system or send the study to the Archive (this applies only to tests in the queue; once in the Archive, the test will still be displayed in the Study list and can be reviewed at any point or another report generated). It is advised to review the information on all three tabs before printing a report.

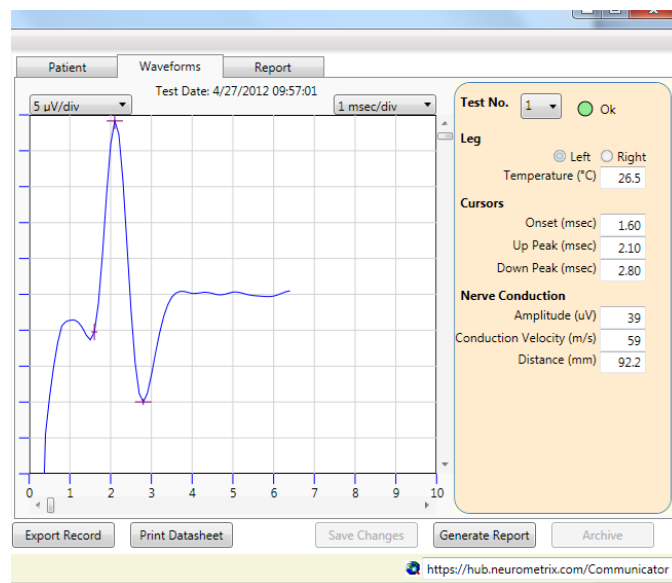
Patient is for entering the Gender, First Name, Last Name, ID, and Birth Date, Height and Weight.

The screenshot shows the 'Patient' tab of the software interface. It contains the following fields and values:

- Gender: ☐ Female ☒ Male ☐ Unknown
- First Name:
- Last Name:
- Subject ID:
- Birth Date:
- Age:
- Height(inches):
- Weight(pounds):

At the bottom, there are buttons for 'Export Record', 'Print Datasheet', 'Save Changes', 'Generate Report', and 'Archive'. A status bar at the bottom right shows the URL: <http://portal1:120/communicator/>.

Waveforms displays the sensory nerve action potential (SNAP) waveform(s) captured in the patient test.



Graph (left)

Set the scale of both axes (time in m/sec on the horizontal axis and amplitude in μV on the vertical axis).

These can be adjusted using the drop down menus above.

Results (right)

View results from the study, including the numbers for Conduction Velocity and Amplitude that were displayed on the device following the test, as well as the values for SNAP onset and peaks as marked with cursors on the graph.

Report allows you to enter in the Physician, Practice, Address, Test Purpose, Technician, and Interpretation that will be included on the printed report. If user selected Show Severity Scale or Interpretation Guide on the **Settings > Report** tab, the Severity Scale or Interpretation Guide will display on this tab and on the report.

Note: If you enter your practice information under **Settings > Report** tab (Physician, Practice, and Address), this information will auto-populate for each study. The Notes button opens a window containing the Interpretation Notes Library. Clicking on an interpretation note in this window will automatically add it to the Notes window on the Report tab. See Section 3.4 for details on creating Interpretation Notes.

Shown with Severity Scale

The screenshot shows the 'Report' tab of the Communicator software. It contains the following fields and elements:

- Tabs:** Patient, Waveforms, Report (selected).
- Patient Information:**
 - Date: 4/27/2012 09:57:01
 - Physician: Jane Washington, M.D.
 - Practice: Main Street Primary Care
 - Address: 100 Main Street,
 - City, State Zip: Any Town, MA 98765
 - Test Purpose: (empty field)
 - Technician: Tim Shaw
- Severity Scale Table:**

Severity	Amplitude	CV
Normal	Normal	Normal
Mild	Normal	Abnormal
Moderate	Abnormal	Normal or Abnormal
Severe	Undetectable	
- Test Results (Left Leg):**
 - Amplitude(μ V): 39
 - Conduction Velocity(m/s): 59
- Interpretation:**
 - ☒ Normal
 - ☐ Mild DPN
 - ☐ Moderate DPN
 - ☐ Severe DPN
 - ☐ Other
- Notes:**
 - Notes button
 - Text area containing: This is a normal nerve conduction study.
- Buttons:** Export Record, Print Datasheet, Save Changes, Generate Report, Archive.
- Footer:** <http://portal1:120/communicator/>

Shown with Interpretation Guide

Patient Waveforms Report

Date: 1/7/2014 2:17 PM
 Physician: Jane Washington, MD
 Practice: Main Street Primary Care
 Address: Main Street
 City, State Zip: Anytown, MA 98765
 Test Purpose:
 Technician: Tim Shaw

	Right Leg	Normal Limit
Amplitude(μ V)	18	3
Conduction Velocity(m/s)	61	46

Interpretation Guide

Interpretation: ☒ Normal ☐ Mild DPN ☐ Moderate DPN ☐ Severe DPN ☐ Other

Notes: Normal Nerve Conduction Study

Export Record Print Datasheet Save Changes Generate Report Archive

Shown without Severity Scale

Patient Waveforms Report

Date: 4/27/2012 09:57:01
 Physician: Jane Washington, M.D.
 Practice: Main Street Primary Care
 Address: 100 Main Street,
 City, State Zip: Any Town, MA 98765
 Test Purpose:
 Technician: Tim Shaw

	Left Leg
Amplitude(μ V)	39
Conduction Velocity(m/s)	59

Interpretation: ☒ Normal ☐ Mild DPN ☐ Moderate DPN ☐ Severe DPN ☐ Other

Notes: This is a normal nerve conduction study.

Export Record Print Datasheet Save Changes Generate Report Archive

<http://portal1:120/communicator/>

Save Changes is a button located at the bottom of the screen in the middle. Users should select this button whenever changes have been made.

NC-stat DPNCheck Communicator

File Studies Settings Help

Queue
10/24/2012 17:55, M Jones

Archive
Today 11/25/2012
November (excluding today)
Prior Months
10/24/2012 13:53, M MacDoanld
10/24/2012 13:01, D H
10/19/2012 16:01, B James
10/19/2012 16:00, M Ford
10/19/2012 15:42, J Doe
9/14/2012 12:22, J Doe
5/10/2012 12:34, R Sawyer
5/10/2012 12:19, M Jones
5/10/2012 11:20, R Stevens
5/10/2012 11:08, C Adams
5/10/2012 10:32, T Trent
4/27/2012 09:57, J Doe
4/27/2012 09:55, K Hancock
4/27/2012 09:49, J Johnson
2/29/2012 13:14, S Quinn
2/29/2012 11:42, G Harris

Patient Waveforms Report

Date 10/24/2012 05:55:26
Physician Jane Washington, M.D.
Practice Main Street Primary Care
Address 101 Main Street
City, State Zip Any Town, MA 98765
Test Purpose
Technician Tim Shaw

Severity	Amplitude	CV
Normal	Normal	Normal
Mild	Normal	Abnormal
Moderate	Abnormal	Normal or Abnormal
Severe	Undetectable	

Right Leg
Amplitude(uV) 4
Conduction Velocity(m/s) 61

Interpretation: ☐ Normal ☐ Mild DPN ☒ Moderate DPN ☐ Severe DPN ☐ Other

Notes
Nerve conduction data is consistent with moderate neuropathy.

Export Record Print Datasheet **Save Changes** Generate Report Archive

Idle http://portal1:120/communicator/

Generate Report is a button located at the bottom right side of the screen. Users should select this button when all the necessary information has been captured in the Patient, Waveforms, and Report tabs. Selecting the button will generate a PDF of the study report which will be displayed on your screen. Once created, the PDF file may be printed. The PDF is automatically saved to the Datastore, emailed or saved to a specific folder. A report can be generated for tests located in either the Queue or Archive.

NC-stat DPNCheck Communicator

File Studies Settings Help

Queue

10/24/2012 17:55, M Jones

Archive

Today 11/25/2012

November (excluding today)

Prior Months

10/24/2012 13:53, M MacDoanld

10/24/2012 13:01, D H

10/19/2012 16:01, B James

10/19/2012 16:00, M Ford

10/19/2012 15:42, J Doe

9/14/2012 12:22, J Doe

5/10/2012 12:34, R Sawyer

5/10/2012 12:19, M Jones

5/10/2012 11:20, R Stevens

5/10/2012 11:08, C Adams

5/10/2012 10:32, T Trent

4/27/2012 09:57, J Doe

4/27/2012 09:55, K Hancock

4/27/2012 09:49, J Johnson

2/29/2012 13:14, S Quinn

2/29/2012 11:42, G Harris

Patient

Waveforms

Report

Date: 10/24/2012 05:55:26

Physician: Jane Washington, M.D.

Practice: Main Street Primary Care

Address: 101 Main Street

City, State Zip: Any Town, MA 98765

Test Purpose:

Technician: Tim Shaw

Severity	Amplitude	CV
Normal	Normal	Normal
Mild	Normal	Abnormal
Moderate	Abnormal	Normal or Abnormal
Severe	Undetectable	

Right Leg

Amplitude(uV): 4

Conduction Velocity(m/s): 61

Interpretation: ☐ Normal ☐ Mild DPN ☒ Moderate DPN ☐ Severe DPN ☐ Other

Notes: Nerve conduction data is consistent with moderate neuropathy.

Export Record Print Datasheet Save Changes **Generate Report** Archive

Idle

<http://portal1:120/communicator/>

Archive is a button located at the bottom right side of the screen. Users should select this when the study is complete in the Queue and they would like to save the patient study in the Archive.

NC-stat DPNCHECK Communicator

File Studies Settings Help

Queue

- 10/24/2012 17:55, M Jones

Archive

- Today 11/25/2012
- November (excluding today)
- Prior Months
 - 10/24/2012 13:53, M MacDoanld
 - 10/24/2012 13:01, D H
 - 10/19/2012 16:01, B James
 - 10/19/2012 16:00, M Ford
 - 10/19/2012 15:42, J Doe
 - 9/14/2012 12:22, J Doe
 - 5/10/2012 12:34, R Sawyer
 - 5/10/2012 12:19, M Jones
 - 5/10/2012 11:20, R Stevens
 - 5/10/2012 11:08, C Adams
 - 5/10/2012 10:32, T Trent
 - 4/27/2012 09:57, J Doe
 - 4/27/2012 09:55, K Hancock
 - 4/27/2012 09:49, J Johnson
 - 2/29/2012 13:14, S Quinn
 - 2/29/2012 11:42, G Harris

Patient Waveforms Report

Date: 10/24/2012 05:55:26

Physician: Jane Washington, M.D.

Practice: Main Street Primary Care

Address: 101 Main Street

City, State Zip: Any Town, MA 98765

Test Purpose:

Technician: Tim Shaw

Severity	Amplitude	CV
Normal	Normal	Normal
Mild	Normal	Abnormal
Moderate	Abnormal	Normal or Abnormal
Severe	Undetectable	

Right Leg

Amplitude(uV): 4

Conduction Velocity(m/s): 61

Interpretation: ☐ Normal ☐ Mild DPN ☒ Moderate DPN ☐ Severe DPN ☐ Other

Notes: Nerve conduction data is consistent with moderate neuropathy.

Export Record Print Datasheet Save Changes Generate Report **Archive**

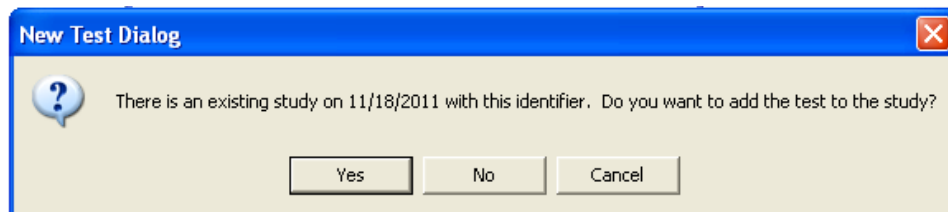
Idle

http://portal1:120/communicator/

3.3 Data Transfer & Report Generation

Transferring Data from NC-stat DPNCheck Device to Communicator

1. To transfer data from the NC-stat DPNCheck device to the Communicator software, first ensure that the Communicator application has been started on the PC. If not already on, power on device. Plug in device to the computer using the USB cable. For USB instructions, refer to Appendix B. This information is also included in the NC-stat DPNCheck device User Manual. Note: Even if the device has powered off, the most recent test is saved and may be transferred.
2. After connecting the device and PC with the USB cable, the device LCD screen will display PC. If the red light on the device appears during this step, the data could not be transferred.
3. The Patient ID dialogue box will appear once the data is ready for entry into the Communicator software. Note: If the ID you enter matches another study in your data queue, the following dialog box will appear. Select **Yes** or **No** to proceed. Select **Cancel** to return to the previous screen. In addition, if you select **Cancel** at this stage, you will need to disconnect and re-connect your device to start transfer process again as it will not save any of the data imported from the prior test. To add the most recent test, select **Yes**. Note: Users may want to do this to combine multiple tests of a patient into one report for one Patient ID (e.g. if testing both Right and Left limbs). This action can only be completed when the test is located in the **Queue**.



4. Next, the Communicator home screen will appear with the data from the uploaded test screen on the **Report** Tab. On this tab users can:
 - Select Gender
 - Enter Patient Name
 - Enter Patient's Birth Date (this will automatically populate the patient's age in the box below)
 - Enter Patient Height
 - Enter Patient Weight

NC-stat DPNCheck Communicator

File Studies Settings Help

Queue
10/24/2012 17:55, M Jones

Archive
Today 11/25/2012
November (excluding today)
Prior Months
10/24/2012 13:53, M MacDoanld
10/24/2012 13:01, D H
10/19/2012 16:01, B James
10/19/2012 16:00, M Ford
10/19/2012 15:42, J Doe
9/14/2012 12:22, J Doe
5/10/2012 12:34, R Sawyer
5/10/2012 12:19, M Jones
5/10/2012 11:20, R Stevens
5/10/2012 11:08, C Adams
5/10/2012 10:32, T Trent
4/27/2012 09:57, J Doe
4/27/2012 09:55, K Hancock
4/27/2012 09:49, J Johnson
2/29/2012 13:14, S Quinn
2/29/2012 11:42, G Harris

Patient Waveforms Report

Gender: ☐ Female ☒ Male ☐ Unknown

First Name:

Last Name:

Subject ID:

Birth Date:

Age:

Height(inches):

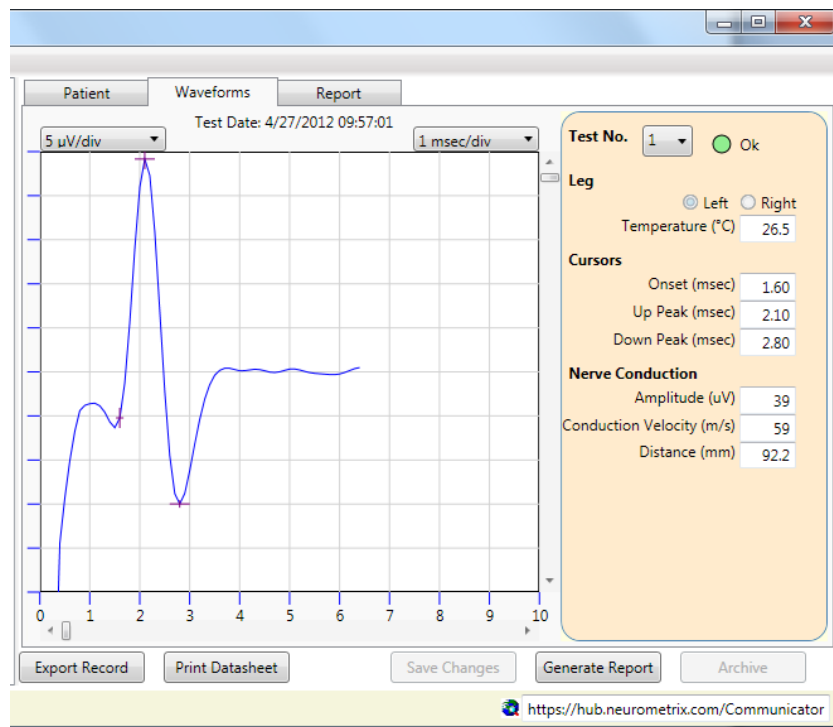
Weight(pounds):

Export Record Print Datasheet Save Changes Generate Report Archive

Idle <http://portal1:120/communicator/>

5. If desired, you can click on **Waveform** Tab. On this tab users can:

- View waveforms, adjust display settings, view skin surface temperature, and view nerve conduction details. Cursor settings can also be edited within this tab if the user has enabled this feature.



6. Next, click on the **Report** Tab. On this tab users can:

- If needed, select a different physician from the Physician drop down menu.
- Enter the Test Purpose.
- If needed, select a different technician from the Technician drop down menu.
- Select an interpretation.
- Click on the **Notes** button which opens a window with the Interpretation Notes library. Click on the desired note to enter that note in the **Notes** section. See Section 3.4 for details on creating an Interpretation Notes Library.

The screenshot displays the 'NC-stat DPNCHECK Communicator' application window. The interface is divided into several sections:

- Left Panel (Queue/Archive):** Lists patient records with dates and names. The 'Queue' section shows '10/24/2012 17:55, M Jones'. The 'Archive' section lists records from 'Today 11/25/2012' and 'November (excluding today)', including 'Prior Months' with various dates and names like '10/24/2012 13:53, M MacDoanld'.
- Top Tabs:** 'Patient', 'Waveforms', and 'Report' (currently selected).
- Patient Information Form:**
 - Date: 10/24/2012 05:55:26
 - Physician: Jane Washington, M.D. (dropdown)
 - Practice: Main Street Primary Care
 - Address: 101 Main Street
 - City, State Zip: Any Town, MA 98765
 - Test Purpose: (empty field)
 - Technician: Tim Shaw (dropdown)
- Severity/Amplitude/CV Table:**

Severity	Amplitude	CV
Normal	Normal	Normal
Mild	Normal	Abnormal
Moderate	Abnormal	Normal or Abnormal
Severe	Undetectable	
- Right Leg Test Results:**

Right Leg	
Amplitude(uV)	4
Conduction Velocity(m/s)	61
- Interpretation:** Radio buttons for Normal, Mild DPN, Moderate DPN (selected), Severe DPN, and Other.
- Notes:** A text box containing the note: 'Nerve conduction data is consistent with moderate neuropathy.'
- Bottom Buttons:** Export Record, Print Datasheet, Save Changes, Generate Report, and Archive.
- Status Bar:** Shows 'Idle' and the URL 'http://portal1:120/communicator/'.

7. Once all information is entered in the Report Tab, click **Save Changes**.
8. Click on **Generate Report** which will generate a PDF of the study report and display the report on your screen. Once the PDF is created, it is automatically stored in the Datastore and can be printed or emailed.

Sural Nerve Conduction Study

John Smith, M.D.
 Main Street Primary Care
 100 Main Street,
 Any Town, MA 98765
 Test Date: 5/10/2012 12:34:19

Patient Name: Richard Sawyer
 Patient ID: 593762
 Gender: Male
 Birth Date: 5/11/1935

	<u>Left</u>	<u>Normal Limit</u>			
Test Date	5/10/2012				
Amplitude (μ V)	2*	4			
Conduction Velocity (m/s)	53				

Severity	Amplitude	CV
Normal	Normal	Normal
Mild	Normal	Abnormal
Moderate	Abnormal	Normal or Abnormal
Severe	Undetectable	

Left

Interpretation: ☐ Normal ☐ Mild DPN ☒ Moderate DPN ☐ Severe DPN ☐ Other _____

Nerve conduction data is consistent with moderate neuropathy.

 John Smith, M.D.

 Date

Sural Nerve Conduction Study

Jane Washington, MD
Main Street Primary Care
Main Street
Anytown, MA 98765
Test Date: 1/7/2014 2:17 PM

Patient Name: Joe Smith
Patient ID: 1234567
Gender: Male
Birth Date: 1/2/1935

	Right	Normal Limit
Test Date	1/7/2014	
Amplitude (µV)	18	3
Conduction Velocity (m/s)	61	46

Interpretation Guide

Right

Interpretation: ☒ Normal ☐ Mild DPN ☐ Moderate DPN ☐ Severe DPN ☐ Other _____

Normal Nerve Conduction Study

Jane Washington, MD

Date

9. Once all information is entered in the Report Tab, click **Save Changes**.
10. Click on **Archive** to move the study from the Queue to the Archive. Once a study is in the Archive the **Export Record** and **Print Datasheet** buttons will become active.
11. The **Datasheet** is intended to be a document that can be provided to the patient with their sural nerve conduction results and specific instructions that the physician would like to provide for the patient. To print a Datasheet, click on the **Datasheet** button. This will open a new window with the Datasheet form. The results of the current test will be automatically populated on the form. If the patient had a test performed at an earlier date, providing the same Subject ID was used, the date of the prior test will automatically populate on the form. When all information is entered, click **Print** and the Datasheet will be both printed and saved simultaneously.

The sample Datasheet below details the information that can be entered on this form.

Patient Datasheet Contents

Fill-in the form and press the 'Print' button

Left Leg
 Amplitude: 2
 Velocity: 53
☐ Test results are normal
☒ Test results are abnormal

Last Test Date: N/A

Today's Results
☐ Same
☐ Improved
☐ Worse

DPN Treatment Plan

	Achieving Goal	Status	Needs Improvement
Lower A1c	<input type="checkbox"/>		<input checked="" type="checkbox"/>
Lower triglycerides	<input type="checkbox"/>		<input checked="" type="checkbox"/>
Lower weight	<input type="checkbox"/>		<input checked="" type="checkbox"/>
Lower blood pressure	<input checked="" type="checkbox"/>		<input type="checkbox"/>
No smoking	<input checked="" type="checkbox"/>		<input type="checkbox"/>
Protect your feet	<input type="checkbox"/>		<input checked="" type="checkbox"/>
Check feet twice daily	<input type="checkbox"/>		<input checked="" type="checkbox"/>
Wear well-fitting footwear	<input type="checkbox"/>		<input checked="" type="checkbox"/>
Keep feet clean and dry	<input type="checkbox"/>		<input checked="" type="checkbox"/>
Use skin moisturizer	<input type="checkbox"/>		<input checked="" type="checkbox"/>

Medication/Therapy
 Use pain management therapies or take medication(s) to help manage DPN symptoms.

Name	Dose	Description

Referral
☐ Endocrinology
☐ Podiatry
☐ Neurology
 Other: _____

Print Cancel

12. The **Export Record** function will export the study report directly to an EMR system (Section 3.6 for detailed information on this feature).

NC-stat DPNCheck Communicator

File Studies Settings Help

Queue

- Archive
 - Today 11/25/2012
 - November (excluding today)
 - Prior Months
 - 10/24/2012 17:55, M Jones
 - 10/24/2012 13:53, M MacDoanld
 - 10/24/2012 13:01, D H
 - 10/19/2012 16:01, B James
 - 10/19/2012 16:00, M Ford
 - 10/19/2012 15:42, J Doe
 - 9/14/2012 12:22, J Doe
 - 5/10/2012 12:34, R Sawyer
 - 5/10/2012 12:19, M Jones
 - 5/10/2012 11:20, R Stevens
 - 5/10/2012 11:08, C Adams
 - 5/10/2012 10:32, T Trent
 - 4/27/2012 09:57, J Doe
 - 4/27/2012 09:55, K Hancock
 - 4/27/2012 09:49, J Johnson
 - 2/29/2012 13:14, S Quinn
 - 2/29/2012 11:42, G Harris

Patient Waveforms Report

Gender: ☐ Female ☒ Male ☐ Unknown

First Name: Mark

Last Name: Jones

Subject ID: 123456667

Birth Date: 1/1/1960

Age: 52

Height(inches): 70

Weight(pounds): 210

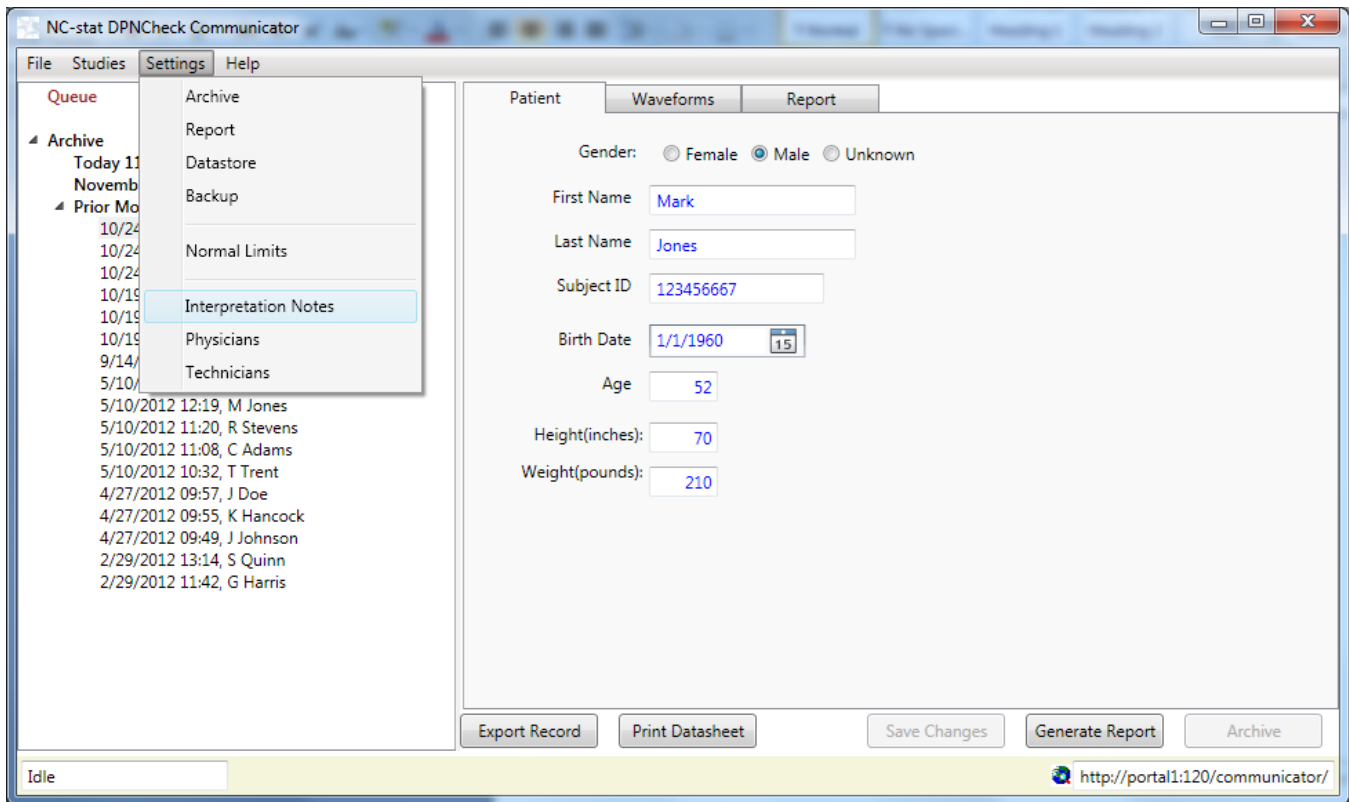
Export Record Print Datasheet Save Changes Generate Report Archive

Idle http://portal1:120/communicator/

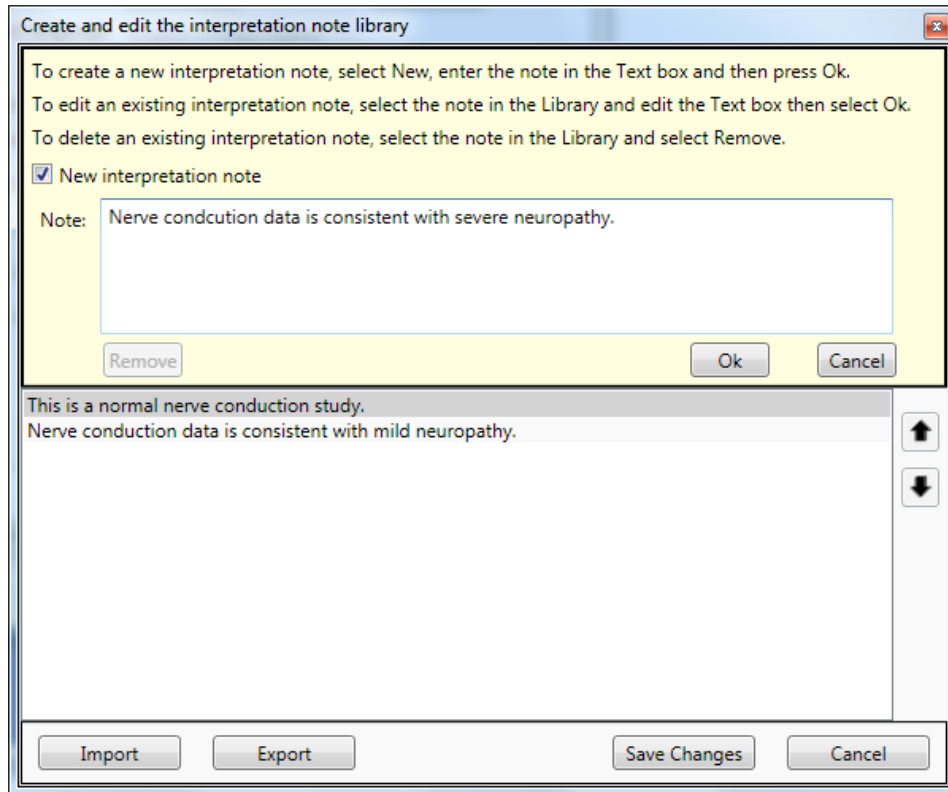
3.4 Using the Interpretation Note Library

Creating Interpretation Notes

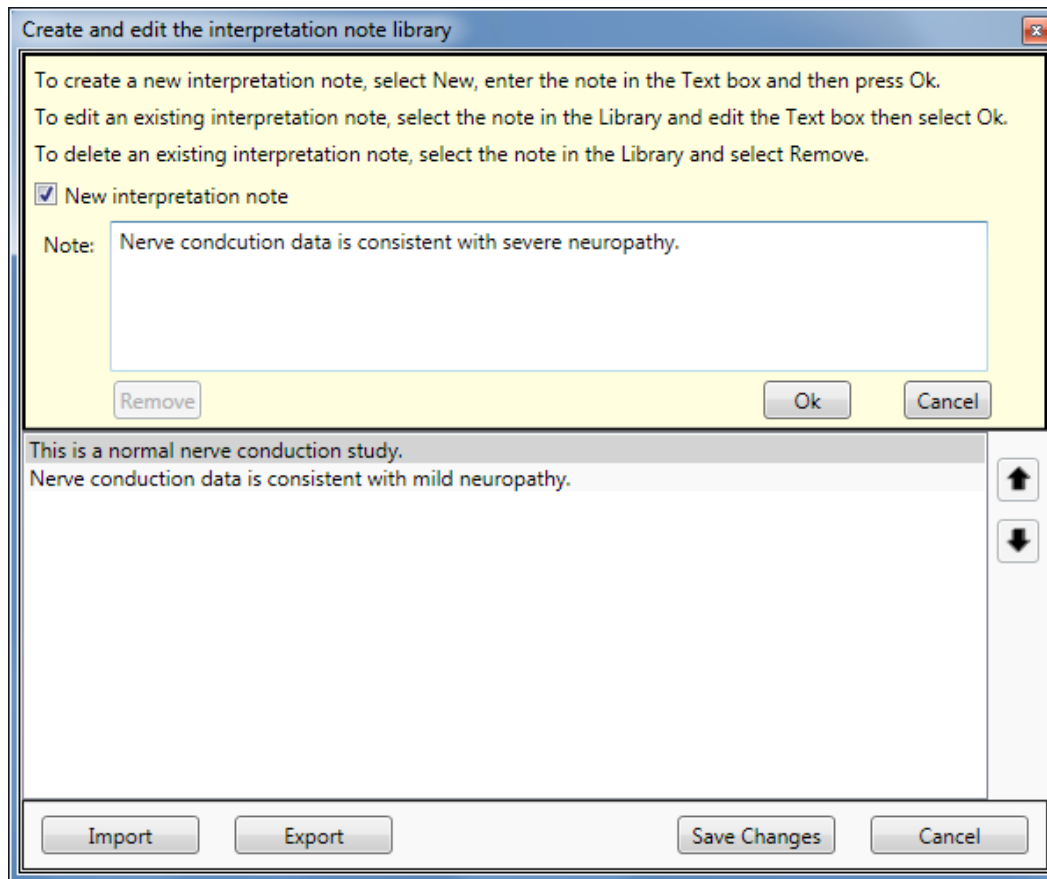
1. To create or edit interpretation notes, select **Settings**, then **Interpretation Notes**.



2. Select **New interpretation note** then enter the text to be saved. Select **Ok**.



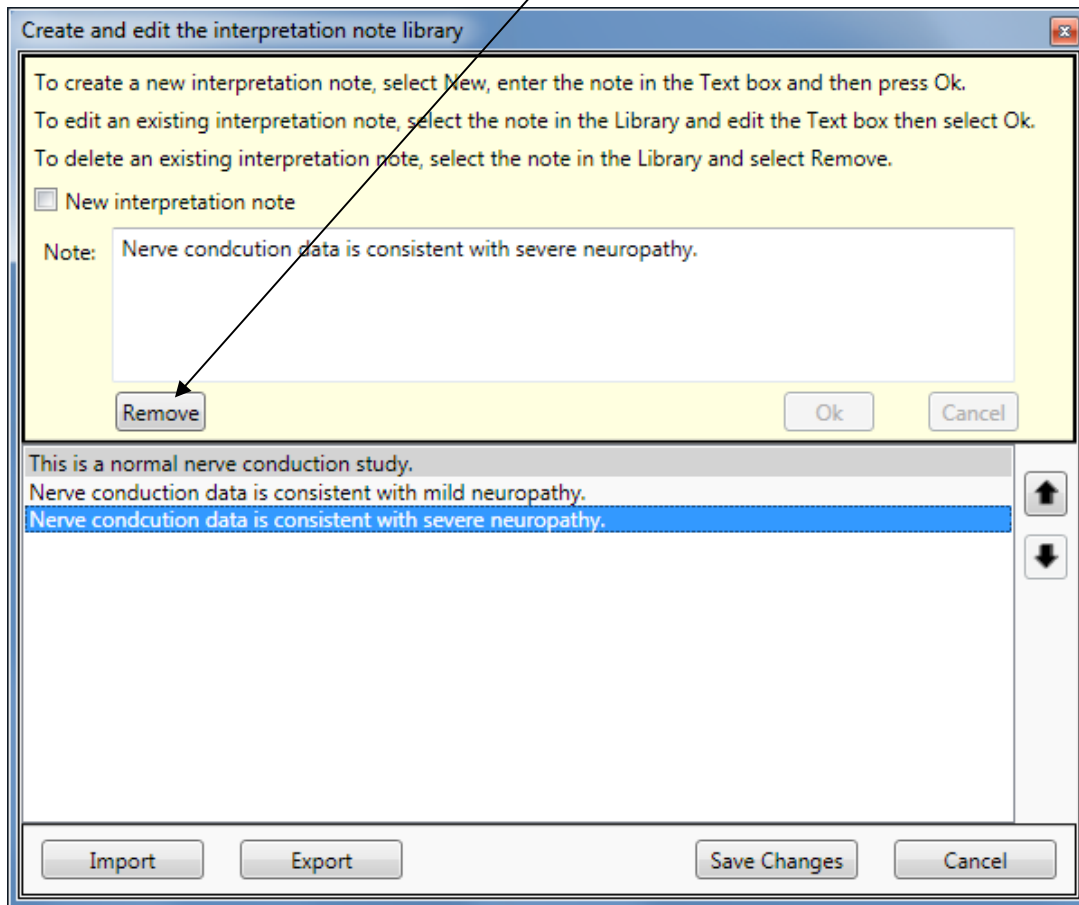
3. The saved note will be moved to the list below. Select **Save Changes**.

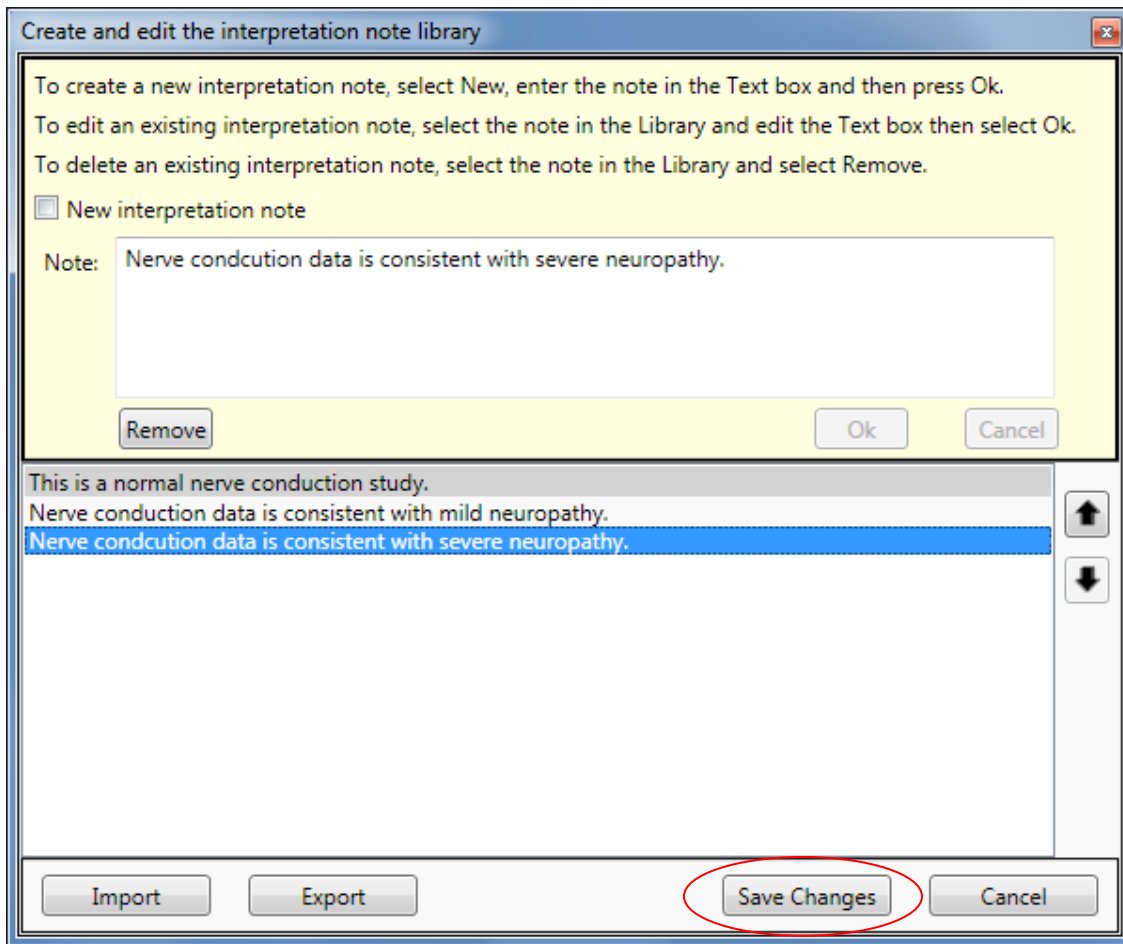


Note: The arrows located in the Interpretation Note Library allows users to change the order of the notes by moving up or down.

Removing Interpretation Notes

1. Select the note to be deleted, then select **Remove**.

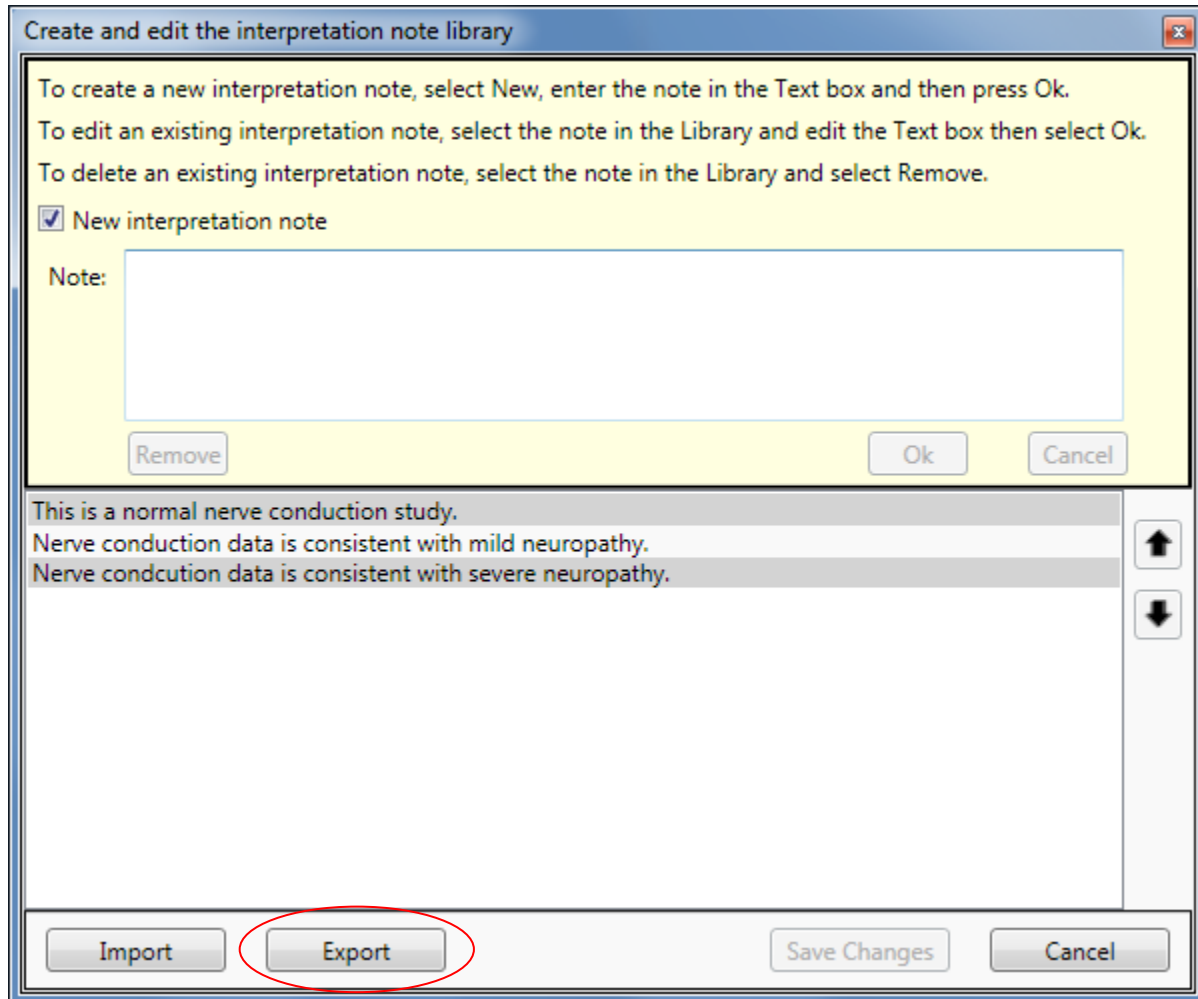


2. Select **Save Changes**.

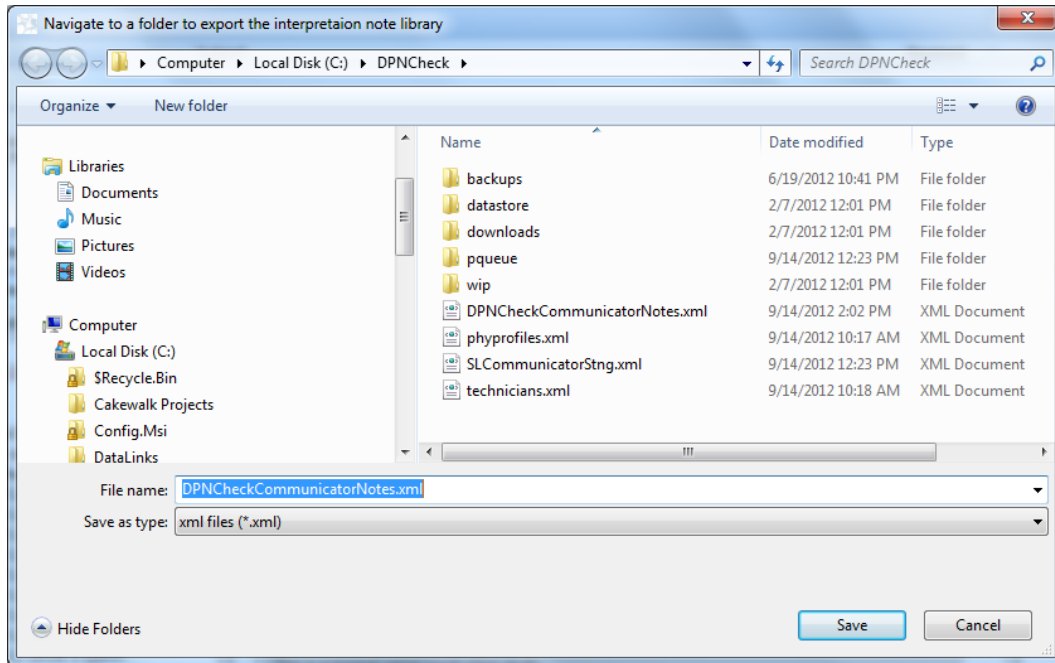
Exporting/Importing Interpretation Notes

Export

1. To export interpretation notes to save on another PC, select **Export**.

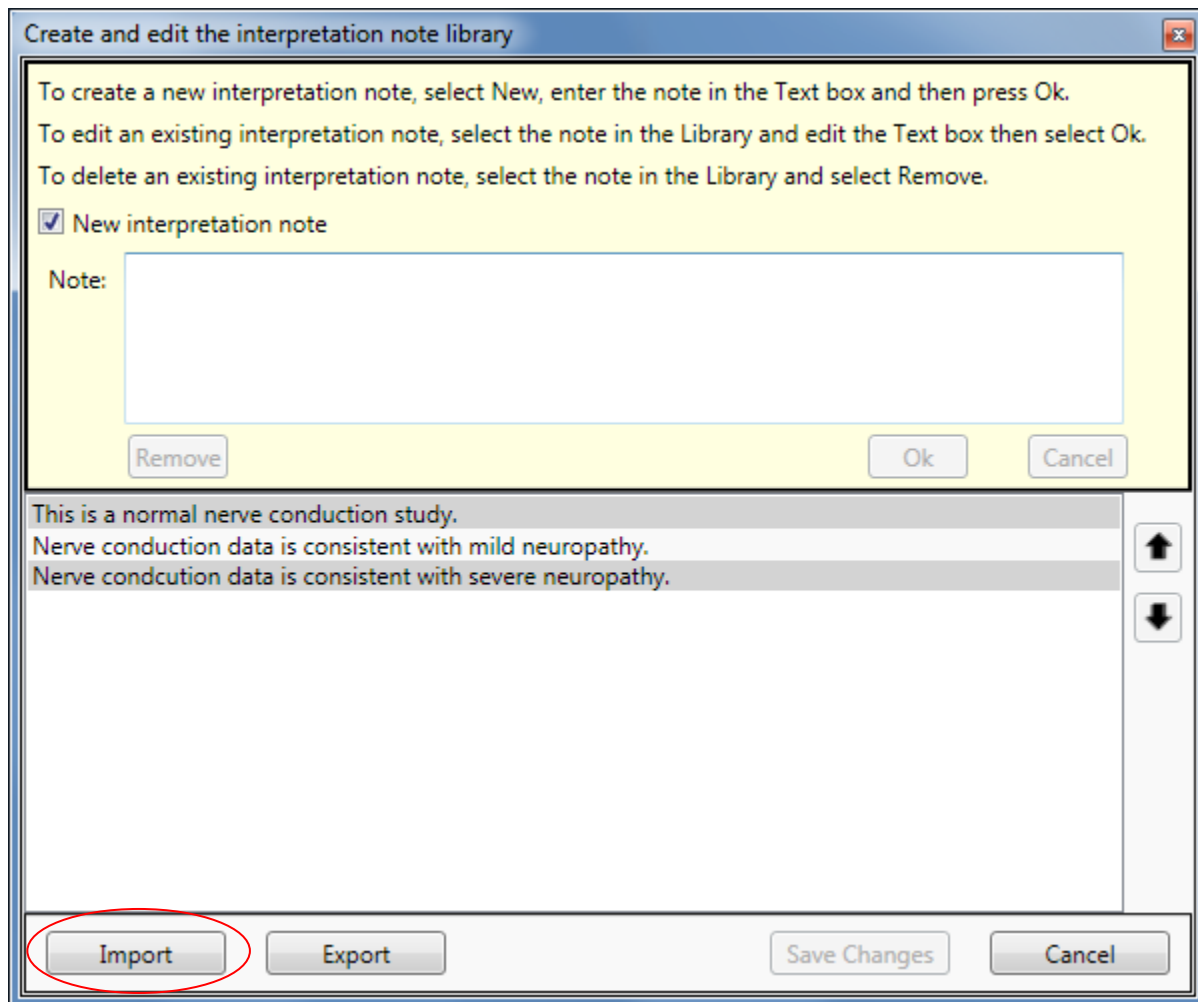


2. Save the file on the C drive.

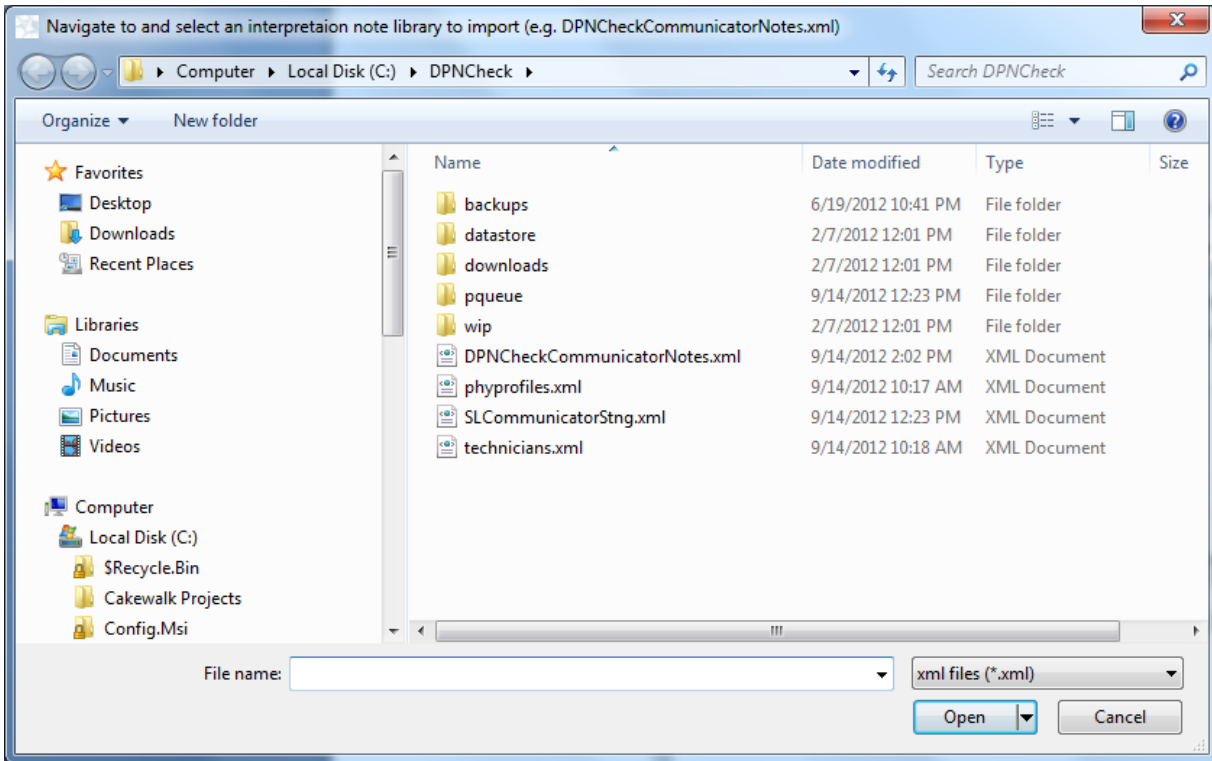


Import

1. To import interpretation notes saved on another PC, select **Import** and open the file to be added.



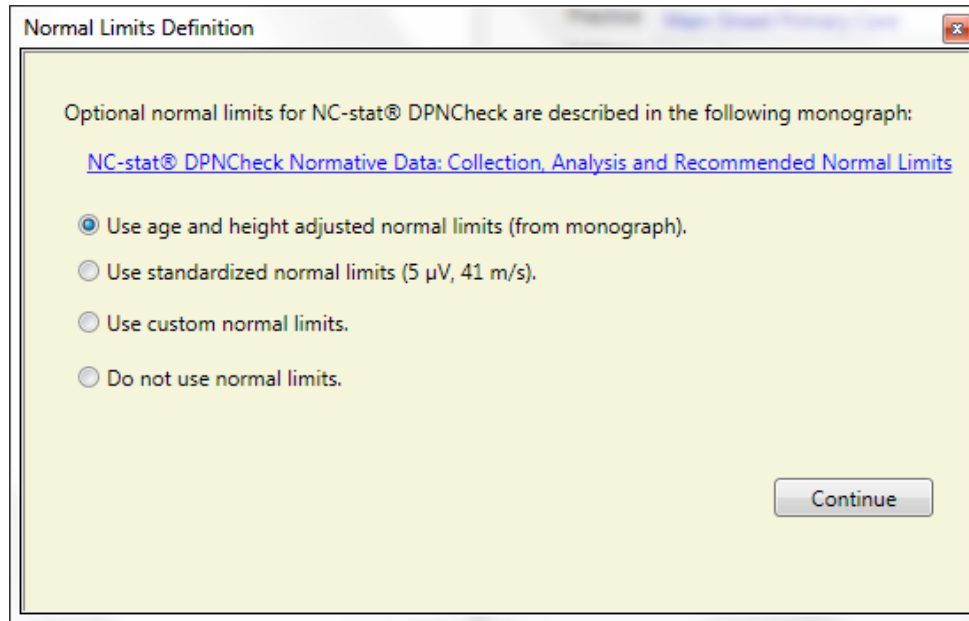
2. Select the file to be imported from your software files.



3.5 Defining Normal Limits

Users can define normal limits for amplitude and conduction velocity within the Communicator software. When these are defined, any amplitude or conduction velocity result that is below the lower limit of normal will be flagged with an * on the Report tab and on the report.

To define normal limits, select **Settings**, then **Normal Limits**.



If user would like to use the normal limits described in the referenced monographs, select “Use age and height adjusted normal limits (from monograph)” and then select **Continue**.

If user would like to use standardized normal limits, select “Use standardized normal limits (5 μ V, 41 m/s)” and then select **Continue**.

If user would like to define different normal limits, select “Use custom normal limits” and then select **Continue**. The following Normal Limit Definitions window will appear:

The image shows a dialog box titled "DPNCheckCommunicator Dialog". It contains two sections for "Normal Limit Definitions".

Amplitude Section:

- Constant:
- Age Coefficient:
- Height Coefficient:
- Check button

Conduction Velocity Section:

- Constant:
- Age Coefficient:
- Height Coefficient:
- Check button

At the bottom of the dialog are two buttons: "Save Changes" and "Cancel".

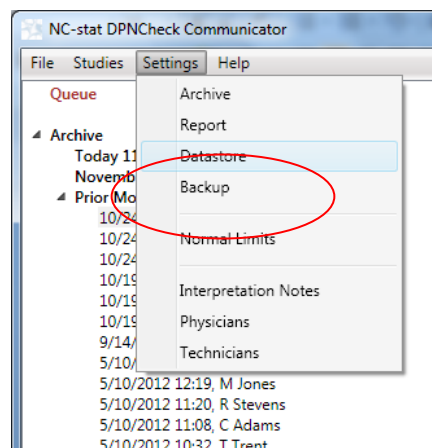
Within the Normal Limit Definitions window enter the values for each Amplitude and Conduction Velocity parameter. Once values are entered the **Check** button will activate. Selecting **Check** will run an integrity check on the normal limit values provided. A pop-up window will appear notifying users if the values entered passed or failed the integrity check. Once the normal limits are defined select **Save Changes**.

If the user does not want normal limits, select "Do not use normal limits" and then select **Continue**.

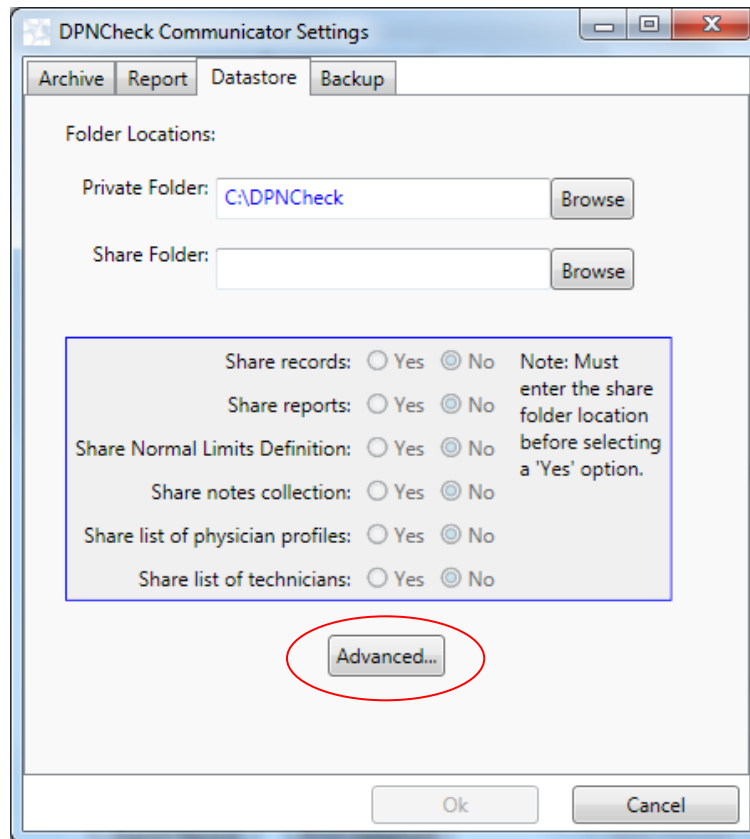
3.6 Exporting Test Reports to an EMR System

Test data can be exported directly to an EMR system. This includes all data fields except the waveform graphics.

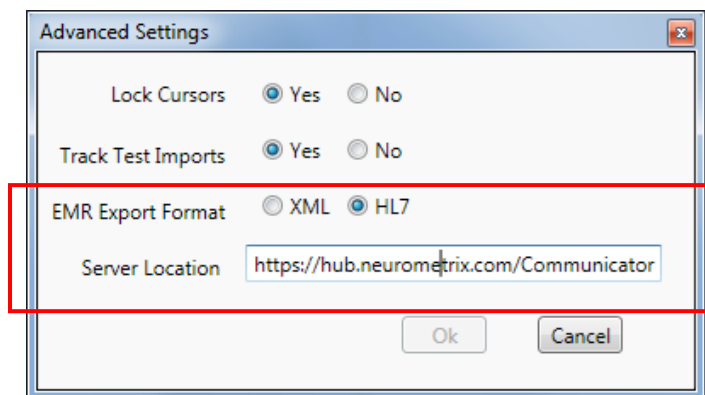
First, set the files type default and serve location by clicking **Settings** on the main menu then click **Datastore**.



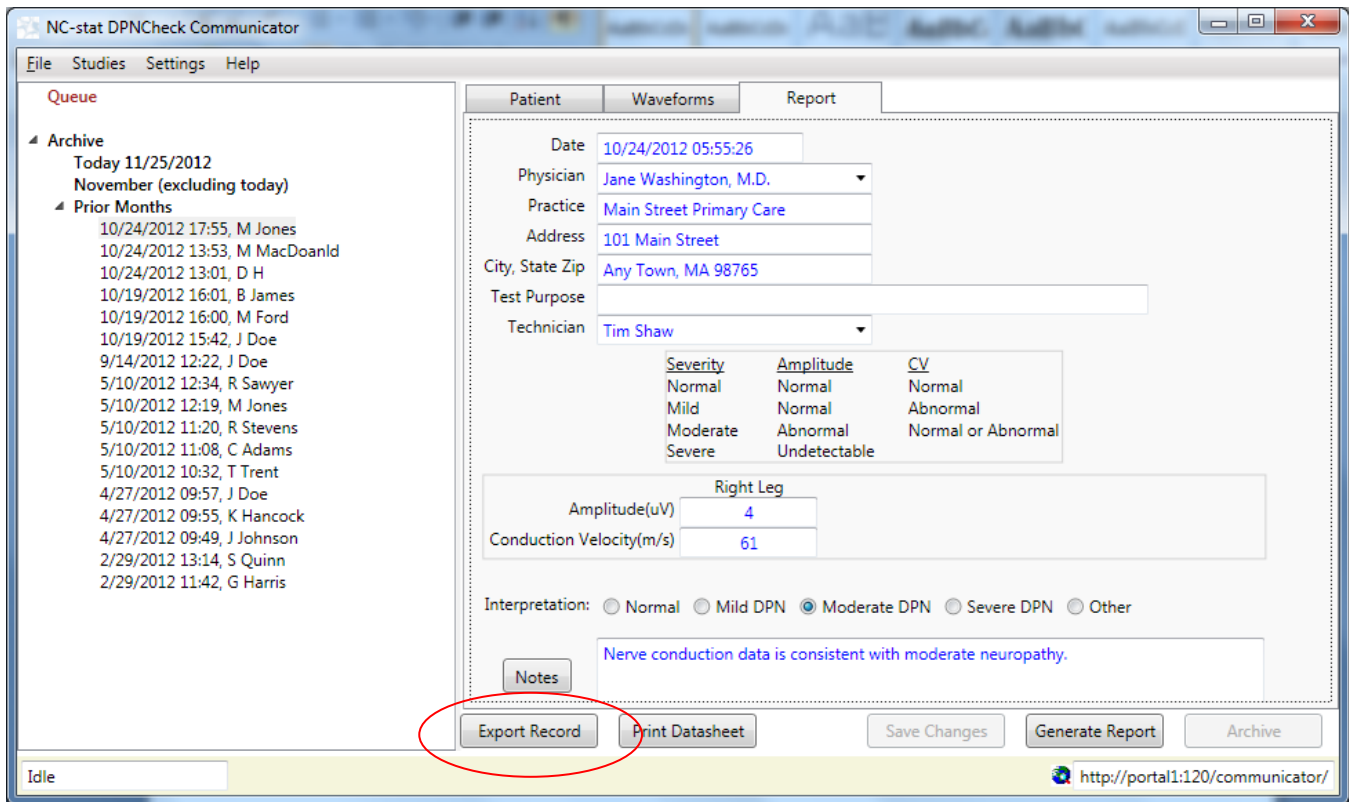
Next, click on the **Advanced** button on the Datastore tab.



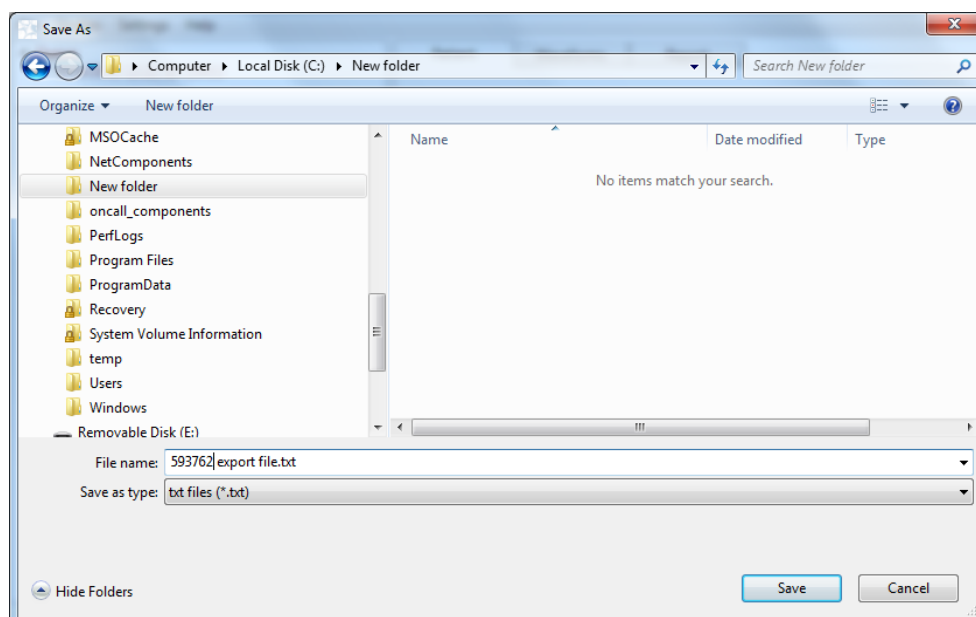
Within Advanced Settings select the **EMR Export Format** and the **Server Location** for the EMR system. When finished, click **OK**. The Communicator is now configured to export reports to your EMR system.



To export a report to the EMR system click on the **Export Record** button.



Next, you will be prompted to name and save the export file. Click **Save** to complete the export process.



3.7 Exporting a Series of Studies Results to Spreadsheet or Database Files

To export a series of nerve conduction results to a spreadsheet or database, select **Studies** from the main menu. Next, select the desired criteria. Then click **Export List**.

The screenshot shows the 'Patients Tested' window. At the top, there are date filters: 'From Date: 4/30/2012' and 'To Date: 9/29/2012', with a 'Count: 6'. The 'Export List' button is circled in red. Below the filters is a table of patient data:

Patient ID	Name	Date	Gender	Age	CV (L)	Amplitude (L)	CV (R)	Amplitude(R)	Interpretat
23453	Doe,John	9/14/2012	Male	52			66.0	8.0	Normal
593762	Sawyer,Richard	5/10/2012	Male	77	53.0	2.0			MildDPN
53854	Jones,Mary	5/10/2012	Female	83			61.0	7.0	Normal
8352	Stevens,Robert	5/10/2012	Male	82			48.0	4.0	Normal
92354	Adams,Catherine	5/10/2012	Female	69	65.0	6.0			Normal
74834	Trent,Thomas	5/10/2012	Male	81	49.0	3.0			MildDPN

Below the table, there is a section for patient details for the selected patient (Doe, John):

Date: 9/14/2012
 Patient: Doe,John ID: 23453 Gender: Male Age: 52
 Physician: Jane Washington, M.D. Practice: Main Street Primary Care

Below the details, there are fields for 'Left' and 'Right' Amplitude and CV:

	Left	Right
Amplitude		8.0
CV		66.0

At the bottom of the window, there are four buttons: 'Export Record', 'Print Datasheet', 'Show Report', and 'Close'.

Next, choose the file destination and name the file and click **Save**. The data will be saved in a csv file format.

CHAPTER FOUR: Safety, Service, FDA Notification and License Agreement

4.1 Safety Notes

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 Service

Should any aspect of the Communicator Software require service, contact NeuroMetrix Customer Service at 1.888.786.7287 or 1.781.890.9989. When you call NeuroMetrix to request service, please be prepared to provide the following information:

- Device model

- Serial number

- Description of the problem

4.3 FDA Notification

The Communicator Software 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, in 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 the NeuroMetrix Customer Service department at 1.888.786.7287 or 1.781.890.9989. Outside of the United States, problems should be reported to the nearest NeuroMetrix distributor. This information will help ensure that NeuroMetrix continues to provide products and services of the highest possible quality.

4.4 NeuroMetrix, Inc. NC-stat® | DPNCheck® Communicator Software License Agreement

1. Proprietary Rights

The software, including without limitation any updates or upgrades thereto provided by NeuroMetrix, Inc. (collectively, the “Software”), and any associated documentation, is subject to the protection of the copyright laws of the U.S. and foreign jurisdictions, which prohibit unauthorized copying and distribution of copyrighted works. The Software and documentation incorporate proprietary and confidential algorithms and techniques of NeuroMetrix, Inc (the “Licensor”) that are subjected to legal protection as trade secrets. The person acquiring and/or using the Software (the “User”) is granted only those rights expressly conferred by the license grant set forth in Section 2 of this license agreement (this “Agreement”).

2. License Grant

Licensor grants the User a license to use the Software and any associated documentation for the User’s personal use or internal business or professional purposes solely as intended to operate and use the NC-stat DPNCheck Communicator, and solely as installed on and/or provided with the NC-stat DPNCheck device purchased from Licensor or its authorized distributor or reseller, consistent with the terms of this Agreement.

3. Reserved Rights

Licensor reserves any rights not expressly granted in Section 2. Without limiting the foregoing, Licensor reserves the right to license the Software and any associated documentation to others on such terms as Licensor may establish in its sole discretion.

4. Restrictions

The User may not:

- a) Copy the Software or documentation in any manner or for any purpose;
- b) Resell or distribute the Software, or any copy, by transfer, lease, loan or any other means, or make it available for use by others in any time-sharing, service bureau or similar arrangement;
- c) Disassemble, decrypt, extract, reverse engineer or reverse compile the Software, or otherwise attempt to discover the confidential algorithms and techniques incorporated in the Software, or disclose or use any confidential information of Licensor in any manner other than as expressly authorized in this Agreement; or
- d) Modify, translate, adapt, or create derivative works from the Software or the documentation.

5. Term

This agreement is effective until terminated. This Agreement and the User's right to use the Software and documentation will automatically terminate without notice in the event of any failure by the User to comply with any of the above restrictions or any term of this Agreement. Upon termination, the User shall return the NC-stat DPNCheck Communicator, including all of the Software and documentation in the User's possession. All provisions of Sections 1, 6, 7 and 8 of this Agreement shall survive termination.

6. Limitation of Liability

In no event will Licensor be liable for personal injury, or any damages including lost profits or other incidental, special, punitive, exemplary, direct, indirect or consequential damages, arising out of or related to the Software, documentation or the use or misuse thereof, even if Licensor has been advised, or is otherwise aware, of the possibility of such damages and even if the warranty remedy of Section 6 fails of its essential purpose. The User and Licensor agree that the Limited Warranty of Section 6 and the Limited Liability of this Section 7 are reasonable in light of the license fees paid under this Agreement.

Some states do not allow exclusion or limitation of liability for personal injury or of implied warranties or limitation of liability for incidental, special, punitive, or other indirect or consequential damages, so the limitations or exclusions of Sections 6 and 7 of this Agreement may not apply to the User. IN SUCH STATES, THE LIABILITY OF LICENSOR SHALL BE LIMITED TO THE GREATEST EXTENT PERMITTED BY LAW.

7. Controlling Law and Severability

This Agreement will be governed by and construed in accordance with the laws of the Commonwealth of Massachusetts, as applied to agreements entered into and to be performed entirely within Massachusetts between Massachusetts residents. This Agreement shall not be governed by the United Nations Conventions on Contracts for the International Sale of Goods, the application of which is expressly excluded. If for any reason a court of competent jurisdiction finds any provision, or portion thereof, to be unenforceable, the remainder of this Agreement shall continue in full force and effect.

8. Export Law Assurances

You may not use or otherwise export or re-export the Software except as authorized by United States law and the laws of the jurisdiction in which the Software was obtained. In particular, but without

limitation, the Software may not be exported or re-exported (a) into (or to a national or resident of) any U.S. embargoed countries or (b) to anyone on the U.S. Treasury Department's list of Specially Designated Nationals or the U.S. Department of Commerce Denied Person's List or Entity List. By using the Software, you represent and warrant that you are not located in, under control of, or a national or resident of any such country or on any such list.

9. Government End Users

The Software and related documentation are "Commercial Items," as that term is defined at 48 C.F.R. §2.101, consisting of "Commercial Computer Software" and "Commercial Computer Software Documentation", as such terms are used in 48 C.F.R. §12.212 or 48 C.F.R. §227.7202, as applicable. Consistent with 48 C.F.R §12.212 or 48 C.F.R. §227.7202-1 through 227.7202-4, as applicable, the Commercial Computer Software and Commercial Computer Software Documentation are being licensed to U.S. Government end users (a) only as Commercial items and (b) with only those rights as are granted to all other end users pursuant to the terms and conditions herein. Unpublished-rights reserved under the copyright laws of the United States.

10. Complete Agreement: Governing Language

This Agreement constitutes the entire agreement between the parties with respect to the use of the Software licensed hereunder and supersedes all prior or contemporaneous understandings regarding such subject matter. No amendment to or modification of this Agreement will be binding unless in writing and signed by Licensor.

Appendix A: Troubleshooting

Description	Possible Issue	Solution
Install Failure	"My software install failed."	If the installation fails for .NET 3.1 components, then you can download from Microsoft's site via the following link: http://www.microsoft.com/download/en/details.aspx?id=22
Device Firmware	"I see a blinking red light on the device and nothing showing on the LCD."	This indicates a bad Firmware on the device and would require a device update. Check for new updates and if there are none then contact Customer Service at (888) 786-7287.
Moving Tests	"I have a patient test that is currently in the Queue, but has not been moved to the Archive."	You are able to move patient studies from the Queue to the Archive by selecting the study in the Studies List and select the Archive button at the bottom right of the screen.
Combining Tests	"I want to combine multiple tests for the same patient that are located in the Archive. Can I do this?"	No. Patient Studies can only be combined when a new test is located in the Queue. You can combine tests in the Queue or Archive by importing a new test and entering the same Patient ID from Archive.

Description	Possible Issue	Solution
Life Time Error	"I received a life time test error message which says the upload of my test failed."	You are unable to import duplicate patient tests. If you received this message, it means you have already imported the patient test that is stored on the device. Look for the patient test in the Queue or Archive. You should also unplug the device from the PC, perform a new test, and import the next test.
Saving a Test	"The test I imported from the device was never saved and I need to import it again."	Unplug the device and plug back into the PC to trigger importing it again.

If you continue to experience technical issues, please call NeuroMetrix Customer Service at (888) 786-7287.

Appendix B: Task Modes

The box located at the bottom left corner of the screen alerts users of the current mode for tasks being performed by the software. Idle will appear when the Communicator is not performing any tasks. The software will remain in this mode for the majority of the time when using the software. Other modes are outlined below:

Backup: this appears when the software is backing up the data based on the automatic or manual backup preferences.

Restore: this appears when the software is restoring the previous settings. You will be asked to restart the software for the changes to take effect.

Appendix C: USB Instructions

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.