DPNCheck®

Reporter Software User Manual

Application Version 2.3

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1 DPNCheck Reporter Overview

The DPNCheck Reporter Software ("Reporter") is a Windows application that allows you to create reports and export DPNCheck nerve conduction data to data management services.

With the Reporter software, you can:
- Store DPNCheck results to a local or networked location.
- Review the physiologic signals recorded by the DPNCheck device.
- Add patient information and physician interpretation to the DPNCheck nerve conduction results.
- Generate PDF reports of the nerve conduction study results.
- Send study results in HL7 format to file or IP address for integration with the EHR.
- Send de-identified results to a cloud database for monitoring and analysis of aggregated data.

2 Applicable Versions

This document describes the functionality for the Reporter software, version 2.3. The Reporter 2.3 application is compatible with DPNCheck models NC-030 (first generation) and NC-040 (second generation).

This user manual document is intended for version 2.3 only and may not apply for other versions of Reporter.

3 Customer Support Contact

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

DPNCheck Cloud Administrator
E-mail: cloudadmin@dpncheck.com

4 Key Terms & Definitions

Term	Definition
Cloud	Refers to the DPNCheck cloud
Communicator	Refers to the Communicator application, which is the predecessor to the Reporter application and has been discontinued.
Device	Refers to the DPNCheck device, first or second generation.
Endpoint	Refers to a PC on which the Reporter Application has been installed.
Export	Refers to a summary of a study (including the embedded PDF Report) in HL7 format for integration into the patient's medical record.
Remote Installation	Refers to an installation process whereby an IT organization can silently push the application to multiple endpoints without requiring end user interaction.
Study	Refers to the collection of test results for a patient collected with the DPNCheck device and uploaded to the DPNCheck Reporter Application. A study file exists for viewing data from within Reporter, and optionally the user may create outputs (PDF report, HL7 export) for incorporation into the patient's Medical Record.
Test	Refers to a sural nerve conduction measurement taken by the DPNCheck device and uploaded to Reporter to create a patient Study.

5   Quick-Start Instructions

Step 1: Connect DPNCheck Device to Upload Data
Start Reporter. Make sure your DPNCheck device is powered on, then connect to the PC. Refer to the DPNCheck device user manual if needed.

Step 2: Enter the Patient ID
Enter a unique ID for the patient; typically this is the Medical Record Number.

Step 3: Enter required Demographic Information on Patient tab (may choose to also enter optional demographic information).
The Patient tab will show asterisks for required fields. The Optional fields will appear in the report and export if filled.

Step 4: Enter optional Physician, Practice, and Technician Information
These fields will appear in the report and export if filled.

Step 5: Clinician Review of Data, addition of Interpretation and Notes
The physician may review the results and provide an interpretation. A selection for neuropathy severity may be made, and additional notes may be added.

Option A: Automatic EHR Integration
Assumes EHR settings configured with "Export to EHR" and "Export when Completing Study" enabled.

> **Step 6 :** Select **Complete**
> An HL7 message is automatically sent to the EHR.
> The Study will move to the Completed list, and an HL7 message, which includes the PDF report, is automatically sent to the EHR.

Option B: Manual Integration

> **Step 6:** Select **Complete**
> The Study will move to the Completed list.
>
> **Step 7:** Select **Report**
> A PDF Report is generated that includes the results, patient and physician information (if provided), and an interpretation (if provided). This may be printed for signature or copied to an alternate location for import into the EHR.

6   PC System and Installation Requirements

The Reporter Software is compatible for installation and use on Windows PCs with Operating System versions 10 or greater.

A minimum .NET version of 4.6 is required for the Reporter application. If the PC does not have this minimum version, .NET will be updated as part of the installation process.

For optimal application display and readability, display settings should be set to the recommended resolution for the PC.

7   Installation

7.1   Important Notes Prior to Installation

General Notes

- Installation and application settings configuration require a coordinated planning effort between the end users and the IT implementation and support team. DPNCheck Recommends that all Reporter Software settings be reviewed prior to installation, to ensure that these may be set appropriately for your organization. It is important to clarify how the settings should be set for your organization to ensure consistent use of Reporter by end users as some settings affect user data entry and display of the test results. See Section 13: Appendix C: Reporter Applications Settings Summary for a detailed list of application settings, and Section 8: Reporter Operation for details of how each setting works in use of Reporter.
- For upgrades from prior versions of Reporter or the discontinued Communicator application, it is generally not necessary to uninstall the previous version prior to upgrade. See Section 7.6: Upgrading from a Previous version of Reporter/Communicator for further detail.
- You must be logged in with Administrator privileges to properly install the software.
- Individual(s) installing the Reporter software should follow their organization's internal security policies and recommendations.

Specific notes on use of the DPNCheck Cloud functionality
The DPNCheck cloud feature sends de-identified patient data to a cloud database for aggregated review. It operates independently from the primary operation of creating reports and exported nerve conduction data for individual patients.

- You will need a DPNCheck assigned Customer ID in order to enable the cloud feature. Customer IDs may be requested from the DPNCheck Cloud Administrator (see contact information Section 3: Customer Support Contact). See Section 8.12: Cloud Data Aggregation for information on this feature.
- An active internet connection is required for use of this feature.

7.2   Install Package

The install package for Reporter version 2.3 is located on the DPNCheck website, www.dpncheck.com/reporter. Separate installation packages are available for Local and Remote installation (see below).

7.3   Installation Options

There are two types of installation available for the Reporter application: Local and Remote (i.e., silent). A local installation installs the application onto a single PC. The Remote installation allows your IT organization to use scripts to install a common configuration of the application to multiple endpoints without end user interaction. See details below regarding the two types of installation.

7.4   Installation Guide – Local Installation

Note: You must be logged in with Administrator privileges to properly install the software.

1. Double-Click **setup.exe** in the install package to initiate the install (be sure the Local Install Package was downloaded). Once the Welcome Screen appears, select **Next.**
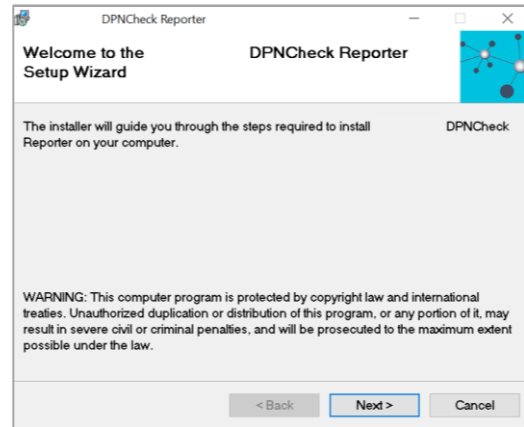
2. Review the DPNCheck Reporter Software License Agreements, select **I Agree**, and then **Next**.

   There are two license agreements to review: DPNCheck Reporter End User License, and DPNCheck Cloud End User License (only applicable if you will be using the cloud functionality, see Section 8.12:Cloud Data Aggregation).

   See www.dpncheck.com/reporter2-3eula/ for full text of the agreements. You must agree to the terms of the agreement(s) before proceeding.
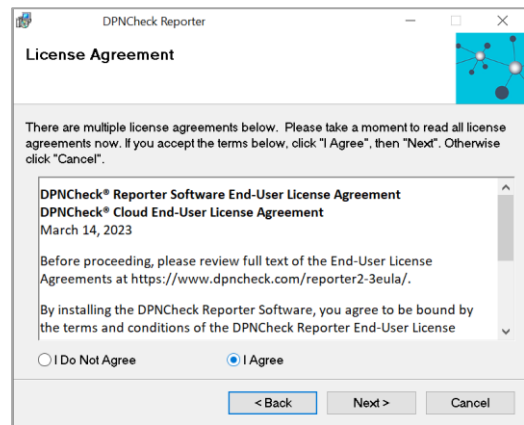
3. Select the Installation Folder. The default creates a folder on the C drive shown here. Select **Next**. To change the folder location, select **Browse** to select the preferred location. The software will now be ready to install on your computer. Select **Next.**
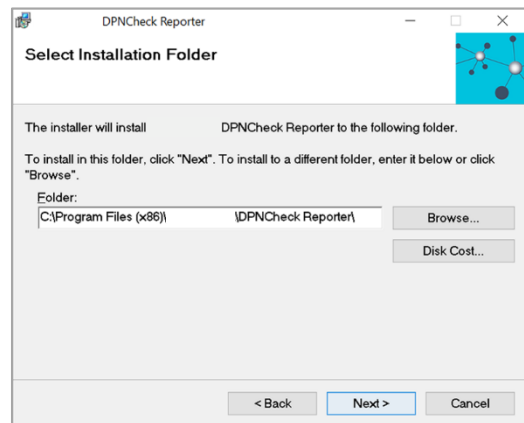
4. Select **Next** to confirm installation.
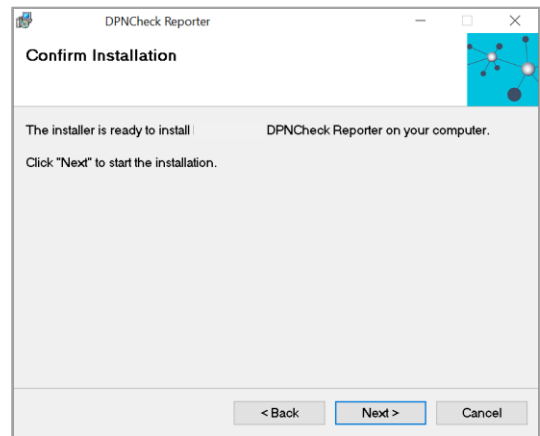
5. A progress screen will appear to update the status of the installation.
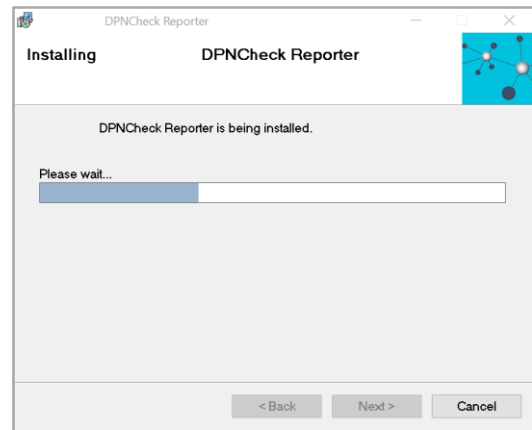
6. The Driver Install screen will appear. Select **Next.**
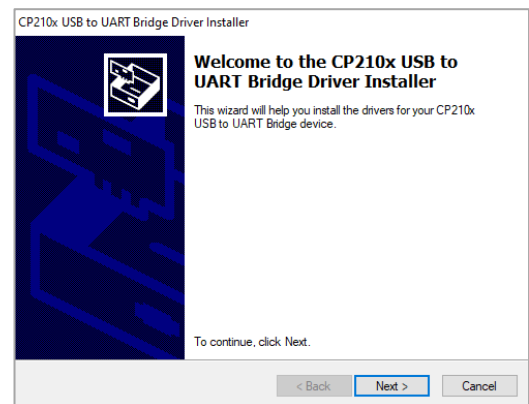
7. Review the License Agreement, select **I accept this agreement** then **Next.**
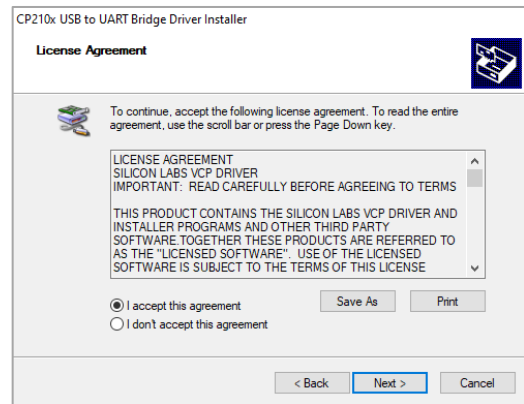
8. Select **Finish.**
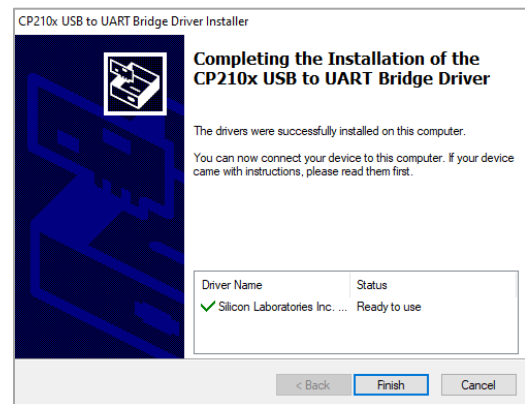
9. The Installation Complete screen will appear when done. Select **Close**. This shortcut icon will appear on the PC desktop:
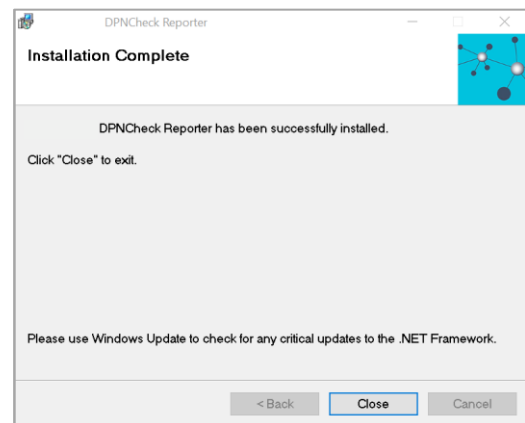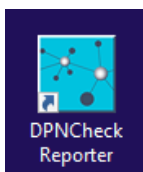
DPNCheck Reporter is now ready to use. Double click the application icon to launch the application.

7.5   Installation Guide – Remote/Silent Installation

A remote installation allows your IT organization to distribute a common configuration (i.e., mirror copies) of the application to multiple endpoints without end user interaction.

7.5.1   Install Packages

For this process, you must download both the Local and Remote Install packages.

7.5.2   Creation of Master Copy via Local Install

First, a master copy of the Reporter Application is created using the Local Install process, see Section 7.4: Installation Guide – Local Installation. This copy will then be mirrored for remotely installing to multiple endpoints.

7.5.3   Configuring Settings of the Master Copy

The Reporter settings should be configured as needed for your organization. See Section 13: Appendix C: Reporter Applications Settings Summary for a description of each setting, and Section 8:Reporter Operation for detail on how these settings function in operation of the Reporter application.

Note: It is important to clarify how the settings should be set within your organization prior to pushing the Remote Install to ensure consistent use of Reporter by end users, as some settings affect user data entry and display of the test results.

7.5.4   Settings Lock (Remote Install Only)

An install via the remote process enables the IT organization to lock select settings so they may not be modified by end users. See Section 13: Appendix C: Reporter Applications Settings Summary for descriptions of the settings which may be locked and Section 14.4: Settings & Process for using Lock settings for instructions on setting up locking. Locked settings can be unlocked and changed by IT but not by the local user.

7.5.5   Performing Remote Install

Once the Master copy with desired application settings configuration is installed locally, that Master Copy may now be pushed silently by IT to multiple remote endpoints. No interaction by endpoint users is required for this process.

Section 14: Appendix D: Remote Installation Notes and Examples provides notes and batch file examples for performing the remote install. These examples are intended to provide an IT organization with sufficient information to create their own remote installation. Your IT organization will determine the best methods to use, such as 3rd party tools and scripting.

7.6   Upgrading from a Previous version of Reporter/Communicator

Reporter version 2.3 supports upgrade either from a previous version of Reporter or from Communicator.

Important Notes regarding upgrade:

- Previous versions of Reporter or Communicator may not coexist on a PC with the new version of Reporter; only one instance is permitted at a time.
- Uninstalling the previous version is generally not required, provided that the second digit in the version number has incremented (e.g., Upgrade from 2.1.1.4 to 2.3 does not require uninstall, 2.1.1.3 to 2.1.1.4 does require uninstall prior to upgrade).
- Reporter version 2.3 supports use of study files (i.e., test results) from previous Reporter and Communicator versions; no data is removed when upgrading to Reporter version 2.3. However, creating a backup prior to upgrade is recommended.
- Back-up and secondary off-system backup of Reporter or Communicator files is recommended prior to performing an upgrade. These files include:
  - C:\DPNCheck
  - C:\Program Files (x86)\DPNCheck
  - Custom Private and Share folder paths set for Reporter; see Section 8.4.1: Datastore Overview for more information on test results saving for Reporter.

NOTE: Downgrading to a prior version of Reporter or Communicator after upgrading to Reporter 2.3 is not supported. If you need to revert to a prior version, contact DPNCheck Customer Support (Section 3: Customer Support Contact).

8   Reporter Operation

8.1   Reporter Workspace and Navigation

The Reporter workspace is divided into panes that allow you to navigate the application to view your DPNCheck test studies, enter information associated with the studies, create reports and exports, and change settings.
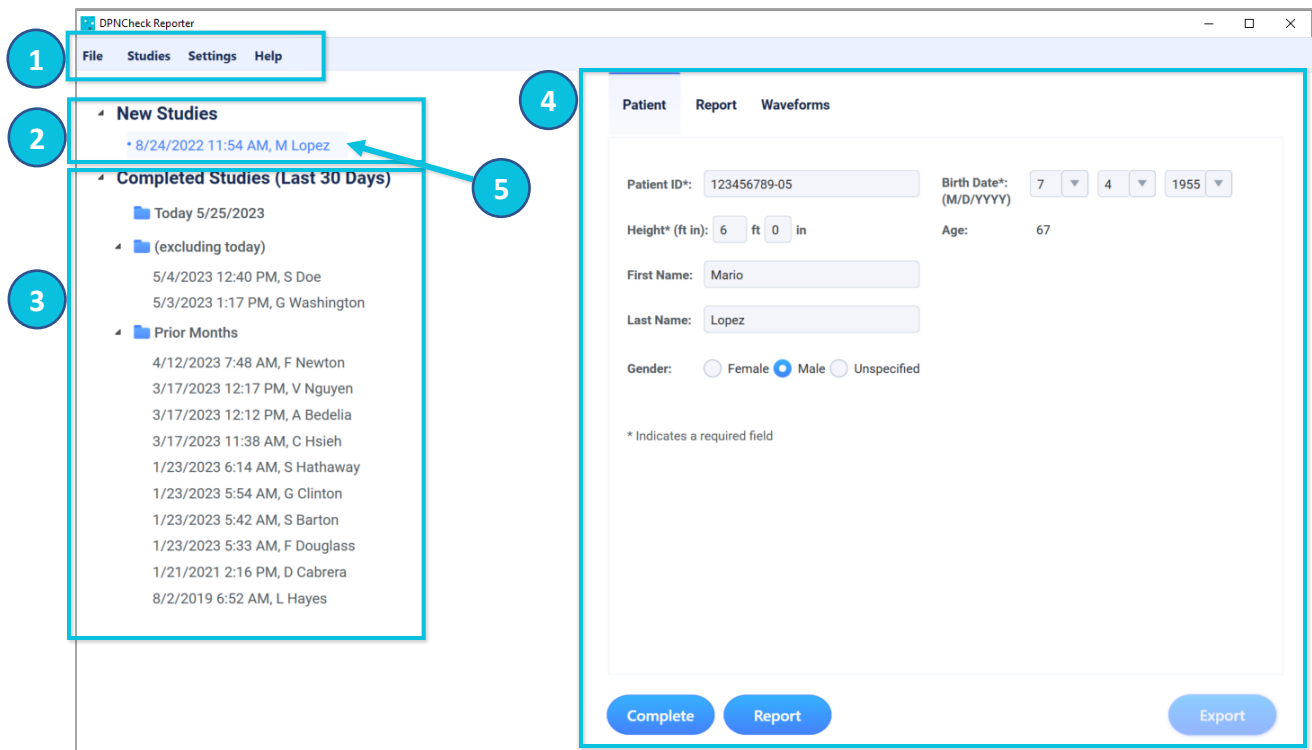
① *Menus:* Menus for File, Studies, Settings, and Help are located here.

② *New Studies List:* When a test is uploaded from a DPNCheck device, it is first located in the New Studies section. This is a staging area for studies that need to be processed by adding patient demographic information and clinical interpretation.

③ *Completed Studies List:* Once the necessary information has been added to the study, the user will click **Complete** to move the study into Completed Studies. From here, reports and exports may be created (see Sections 8.10: Reports, 8.11: Exports and EHR Integration).

④ *Study Window:* When a new study is uploaded or a new or completed study is selected, the study will display in this window. Study data is separated into 3 tabs – Patient, Report and Waveforms.

⑤ *Selected Study:* The active study is highlighted in blue and shown with a dot to the left of the study name in the list.

See below for details on each of these parts of the navigation.

8.1.1　Menus

File Menu: Provides the option to exit the Reporter Application.
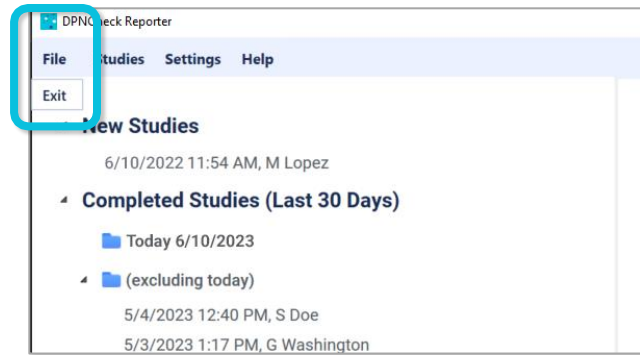
Studies Menu: The Studies section provides various ways to search for a patient report from your New and Completed studies lists. Search options include:

- By Patient Name
- By Patient ID
- By Physician
- By Technician
- By Practice
- By Date Range
- All Studies

See Section 8.13: Study Search for more detail.
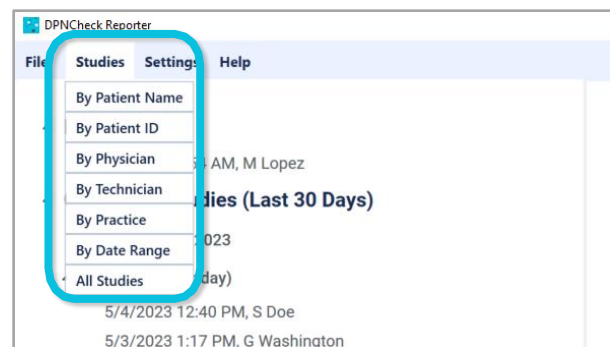
Settings Menu: Settings provides for customization of the following features:

- Completed Studies (Section 8.1.6: Customizing Your Study View)
- Report (Section 8.10: Reports)
- Datastore (Section 8.4: Storing Reporter Studies and Patient Record Outputs)
- EHR (Section 8.11: Exports and EHR Integration)
- Security (Section 9: Security Features and Settings)
- Cloud (Section 8.12: Cloud Data Aggregation)
- Normal Limits (Section 8.5: Normal Limits)
- Interpretation Notes (Section 8.9: Interpretation Notes)
- Physician Lists (Section 8.7: Physicians)
- Technicians Lists (Section 8.8: Technicians)
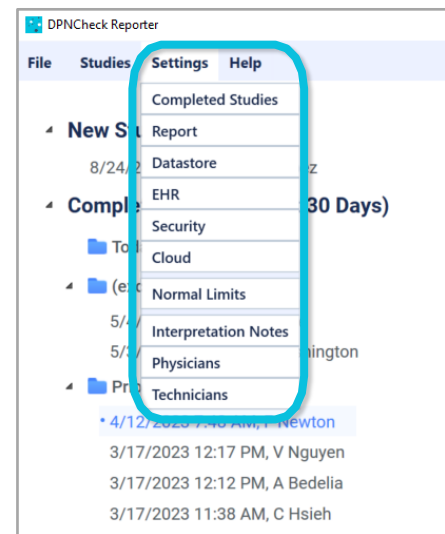
See Section 13: Appendix C: Reporter Applications Settings Summary for a full summary of settings.

Help Menu: Help allows you to access information about the Reporter Application and helpful resources on the DPNCheck website.
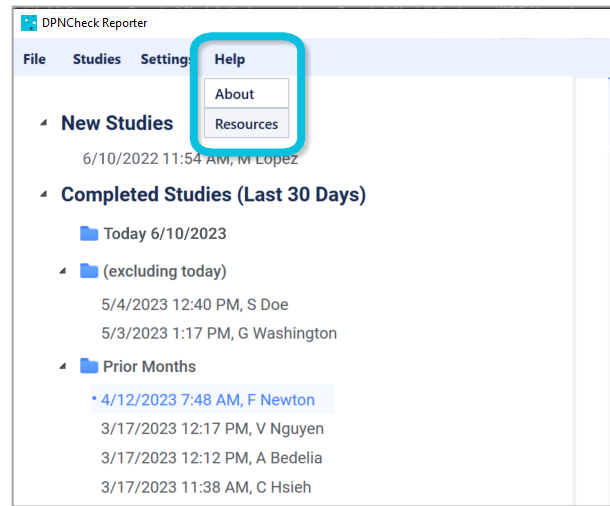
8.1.2 Study Lists

The Study Lists show your Reporter studies. Each is labeled with date of upload, as well as the First Initial and Last Name of the patient (if no name is entered, studies in the list will be labeled by Patient ID).

To view the details of a study, click on the study you wish to view in the Study List. The item will highlight to indicate that it is selected, and the study details will show in the right pane Study Window (see sections below for descriptions of tabs within the Study Window).

If completed studies are exported, the Study List will indicate whether export was successful or failed. See Section 8.11: Exports and EHR Integration for more detail on exports.

8.1.3 Study Window: Patient Tab

All patient identifier and demographic information is entered on this tab. The user may review and update information on this tab; all entries in studies are saved automatically. Required fields are indicated with an asterisk (*). Please note, the fields shown below may not match your display depending on your Normal Limit setting (see Section 8.5: Normal Limits for information about Normal limits).

8.1.4   Study Window: Report Tab

The Report tab allows for entry of Physician and Technician information, displays amplitude and conduction velocity measurements with normal limits, as well as either an Interpretation Guide or Severity Scale. The clinician may select an interpretation and add notes. The physician fields and Guide shown below may not match your display depending on your Report settings (see Section 8.10: Reports for further detail on Report settings).

8.1.5   Study Window: Waveform Tab

The Waveform tab displays the sural nerve waveform(s) and nerve conduction study data as measured by the DPNCheck device. If more than one valid nerve conduction test is associated with this patient, the user may select Test Number to view other tests.

The waveform is marked with red cursors to indicate the onset and peaks used in the conduction velocity and amplitude calculations, respectively.
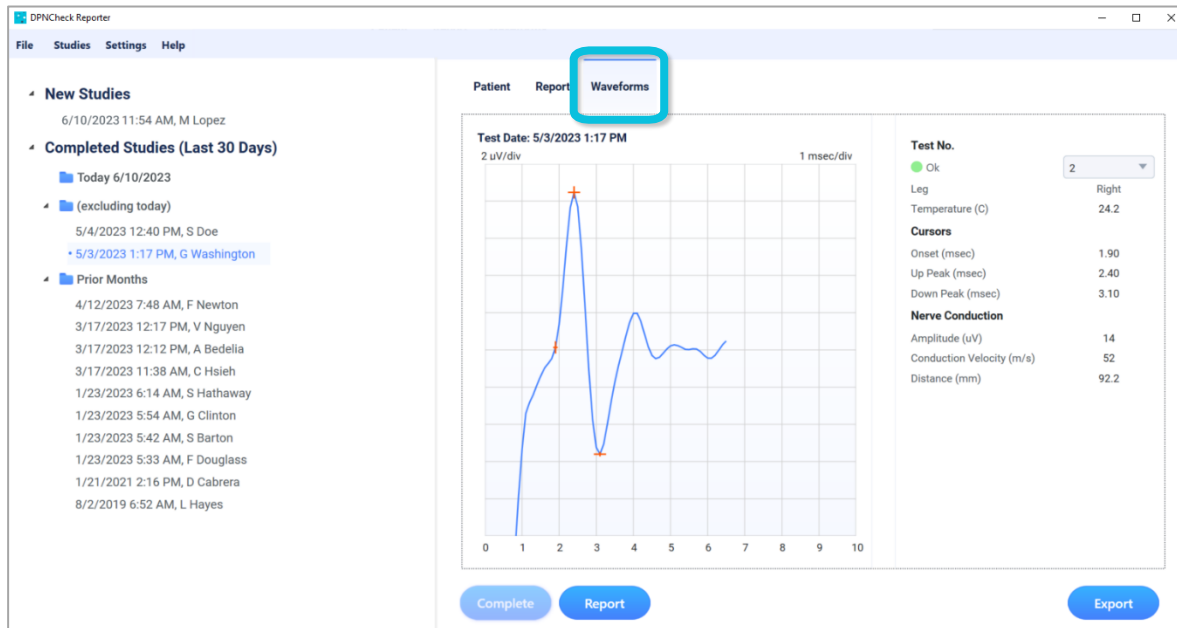
8.1.6   Customizing Your Study View

Completed Studies List: Navigate to the Completed Studies settings, and choose the time period for which studies appear in the Completed Studies list:

- All Available
- Last 10 Days
- Last 30 Days (*Default*)

This setting will control which studies are loaded into the Completed Studies list as well as which studies are shown in a Study Search (see Section 8.13: Study Search).

Note: in the Study List you will only see completed studies from the time period selected in the settings, but older studies are not lost, and they may be viewed by setting to a longer time period.

Note: If Start-Up time of the Application is slow, try setting the Completed Studies setting to a shorter time window; time to load depends both on the number of studies loaded as well as the speed of your network connection.

Date and Time Format: You can modify the Date and Time Format in the Report settings that will appear in the Studies List, Report Tab, Waveforms, and Report. See Section 8.10.3: Report Settings for detail.
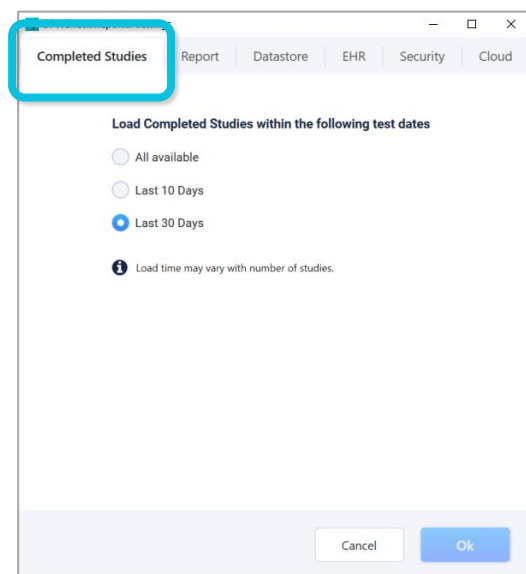
Measurement Units: You can select the Measurement Units in the Report settings that will appear for the Height field on the Patient tab; a change to Measurement Units will be applied for the next uploaded test from the DPNCheck device. See Section 8.10.3: Report Settings for detail. Note that the Height field will only show if entry is required per Normal Limits setting, see Section 8.5: Normal Limits.

8.1.7   Study Window: Action Buttons

1 **Complete** will move a study from New Studies to Completed Studies (button active for new studies only). If Automatic Export is enabled, an export will also be performed with this action.

2 **Report** will generate the PDF report for a completed study.

3 **Export/Send to EHR** will create an HL7 export that is stored as a file in datastore or sent to the EHR, depending on the EHR settings (button active for completed studies only). The PDF report is embedded in the HL7 export.

8.2   Understanding DPNCheck Results

There are generally two results given for the sural nerve conduction performed with the DPNCheck device: amplitude in microvolts and conduction velocity in meters/second. These values will be shown on the Report tab along with normal limits that have been calculated (see Section 8.5 Normal Limits). If either the amplitude or conduction velocity is below the normal limit, the value will be shown with an asterisk (*).

In most cases, the results will contain both amplitude and conduction velocity values. However, in some circumstances, only amplitude will be shown. This is a valid result, and interpretation should be performed based only on the amplitude.

The results in conjunction with the normal limits may be used to evaluate the severity of neuropathy present. Guidelines for severity is as follows (this guide is provided for informational purposes only and does not provide a clinical diagnosis):

Severity Scale

Normal (no neuropathy): both amplitude and conduction velocity are normal.

Mild neuropathy: conduction velocity outside normal limits with normal amplitude.

Moderate neuropathy: amplitude outside normal limits.

Severe neuropathy: undetectable response (i.e., amplitude of 0).

The Report tab will show either an Interpretation Guide or Severity Scale (based on Report settings, see Section 8.10.3 Report Settings) to provide a visual tool for interpretation of the results; these are for information purposes only and do not provide a clinical diagnosis.
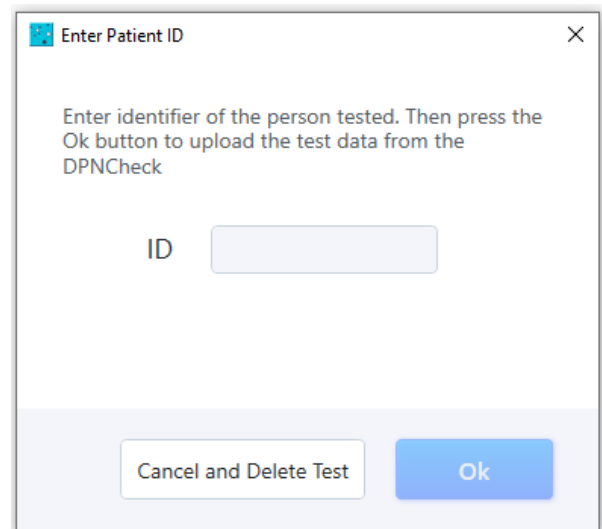
8.3   General Workflow for Using Reporter

There are three basic steps to creating a study and generating documentation needed for incorporation into the patient's medical record:

1. Upload data from the DPNCheck device into New Studies.
2. Enter study information per organizational policies: Patient, Physician, Technician, Interpretation.
3. Complete study, generate patient record documentation outputs, PDF report or HL7 export (includes PDF report).

8.3.1   Upload Test from DPNCheck Device

1. Open the Reporter application on the PC.
2. Use the USB cable provided with the DPNCheck device to connect the device and the PC.
3. If not already powered on, power on the DPNCheck device by pressing the gray button. The device screen will indicate if it is connected to the PC.
4. Once connected, the device will automatically upload the test to Reporter. A pop-up message will be shown for entry of the Patient ID. This should be a unique identifier to associate the study with the patient; typically, the Medical Record Number. An ID must be entered here in order to proceed.

Enter Patient ID dialog box:

Enter identifier of the person tested. Then press the Ok button to upload the test data from the DPNCheck

ID [   ]

Cancel and Delete Test   Ok

PN2205555 Rev E

Note that if you choose to cancel the import by selecting "Cancel and Delete Test", the test may be deleted from the device, and you may need to repeat the DPNCheck test on the patient. Following upload, you will have the ability to change the Patient ID if needed.
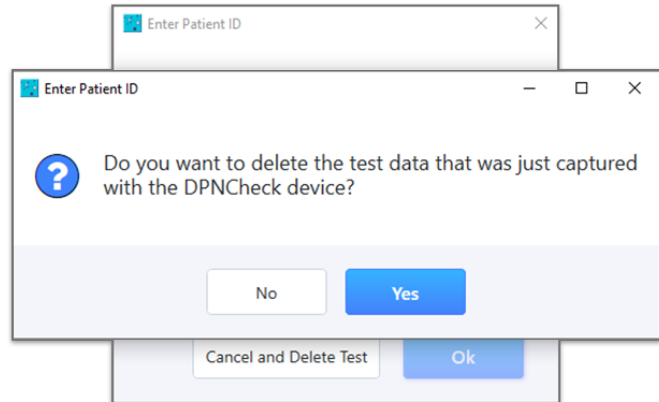
8.3.2   Merging Multiple DPNCheck Tests into a Single Patient Study

If patients are tested bilaterally, the data can be combined for creating a single report or HL7 export (i.e., results from both right and left legs). When uploading a study from the DPNCheck device to Reporter, if the Patient ID entered matches a study in the New Studies list from within the last 5 days, the following message will display:
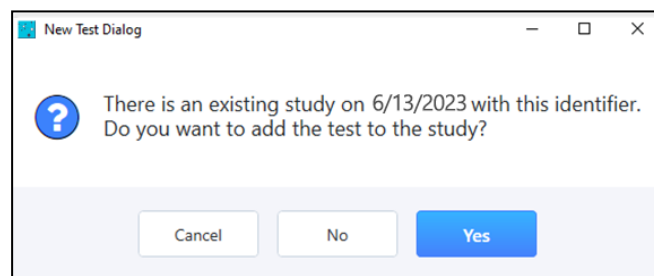
Selecting **Yes** will add the test to the study of the matching Patient ID. If multiple studies meet that criterion, the study containing the most recent test upload will be selected for merge. Selecting **No** will create a new, separate study, in New Studies. Select **Cancel** to return to the Patient ID prompt to re-enter a Patient ID to proceed with import.

If there are multiple tests within a study, a report or export generated for that study will contain results from the most recent left and/or right tests.

8.3.3   Enter Study Information

Data entered into the Patient and Report tabs are used in the generated report and export. See Sections 8.10: Reports and 8.11: Exports and EHR Integration for more detail on how the fields entered are used in generating reports and exports. A study should not be completed until all needed information is entered. Note: Reporter automatically saves all entered data.

Patient Tab Entry

Enter the following on the Patient Tab:

1 **Patient ID:** This will have been previously entered on test upload. It is a required field and will appear on the report and in the export.

2 **Birth Date:** Enter Month-Day-Year by typing or selecting from dropdown. This may be required entry based on Normal Limits setting. The age will automatically be calculated if a valid birthdate is entered. Birth date will appear on the report and in the export if entered.

3 **Height:** Enter in English or Metric units (based on Report settings). This field may not be displayed/required depending on the Normal Limits setting. This field will not appear on the report or export.

4 **First Name:** This field is not required and will appear on the report and in the export if entered.

5 **Last Name:** This field is not required and will appear on the report and in the export if entered.

6 **Gender:** "Unspecified" is selected by default. The selection will appear on the report and in the export.

Fields designated as Required with an asterisk (*) are required for calculation of Normal Limits and display of the Interpretation Guide. Note: if height entry is not required for your Normal Limits selection, the field will not be displayed on the Patient tab.

Report Tab Entry

Enter the following on the Report Tab:

① **Physician and Practice:** Enter or select a physician from the dropdown menu. See Section 8.7 Physicians for information on setting up the Physician List. If entered into the Physician List, NPI number and Practice Information will automatically populate when selecting a physician. If a default physician is specified in the list, this will automatically populate when the study is first created. Note: Practice Information fields (Practice, Address, City, State, Zip) will not be displayed if "Enable Practice Entry" has been disabled in Report settings. Physician and practice information will appear on the report and export if entered. NPI will be included in export if entered, but not the report.

② **Technician:** Enter or select a technician from the dropdown menu. See Section 8.8: Technicians for information on setting up the Technician List. Technician will be included on the report if entered and selected in Report settings. Technician and Technician Email (if included in Technician List) will be included in export if entered.

③ **Interpretation Selection:** Optionally select an interpretation of the severity of Peripheral Neuropathy (PN). The selection will appear on the report and in the export if entered.

④ **Interpretation Notes:** Enter notes or add from notes library (right click in text box); these will appear on the report and in the export if entered. See Section 8.9 Interpretation Notes for information on setting up an Interpretation Notes library.

8.3.4   Complete Study, Generate Patient Record Outputs

Completing the Study

When all required information has been entered as described in the previous section, the study may be completed, and documentation of the results generated as needed for incorporation into the patient's medical record.

Select **Complete** to complete the study; this moves the study from New Studies to Completed Studies. Once completed, a study may not be returned to the New Studies list. While not recommended, you may edit study details for a completed study.

Generating Patient Record Outputs

There are two types of documentation outputs that may be generated for incorporating into the patient's medical record:

- **Report:** Summarizes study in PDF format. See Section 8.10 Reports for more detail.
- **Export:** Summarizes the study in HL7 format which may be saved to a file or sent directly to the EHR. This also incorporates the PDF report. See Section 8.11: Exports and EHR Integration for more detail.
- Your organization should decide which output is appropriate.

Select **Report** to generate the report and open in a PDF viewer. This may be convenient if you wish to print this document for physician signature.

OR

Select **Export** or **Send to EHR** to generate the HL7 export. The HL7 export or output to EHR includes the embedded PDF report, but it is not opened in a PDF viewer when selecting the button.

In EHR settings, you may enable "Export when Completing Study" which will automatically create the export file or send to EHR when you select **Complete** as described above.

8.4   Storing Reporter Studies and Patient Record Outputs

Reporter uses a file system for saving studies and outputs that may be incorporated into the patient's medical record[1].

8.4.1   Datastore Overview

The Datastore setting controls where DPNCheck Reporter data is stored; it may be stored locally or in a network folder. A network location setting can be configured for single or multiple Reporter endpoints (i.e., PCs). The structure of saving data within DPNCheck Reporter, whether locally or to a network folder, prevents commingling of patient-specific results among multiple endpoints.

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[1] The Windows file date is used by Reporter in loading studies. Please note that if study files are moved manually, this may affect the ability of the studies to be loaded into Reporter using the setting selected in Completed Studies settings. Moving study files manually is generally not recommended. However, if it is necessary, using cut and paste is recommended to preserve the Windows file date.

Saving data to a common network location

For enterprise customers, IT can configure a common network folder and assign it to all DPNCheck Reporter endpoints that are members of a group or site, such that IT has a single directory hierarchy to manage Reporter data. This may be helpful in managing administrative tasks such as backups, data collection, or inspection of data at a particular endpoint PC. Use of a common network folder may also be advantageous when internal security policies limit storage of patient data on local systems, and instead require storage of such data to a secure network location.

See Section 15 Appendix E: Using the Same Network Datastore Location

for Multiple Systems for more detail on using the same datastore path for multiple endpoints.

8.4.2 Datastore Setting, Private and Share Folders

The Datastore Setting enables the user to select where DPNCheck Reporter data is stored. By default, all Reporter data will be stored locally under the Private Folder C:\DPNCheck.

Private Folder: The location of the Private Folder can be modified under the Datastore settings. The Private Folder location can be a local directory on the endpoint PC or a network location. The Private Folder is the primary location for storing Reporter study files and must be specified. Under the Private Folder, the Datastore directory and additional sub-folders will be created (see below).

The Private Folder also contains files that are created for the Normal Limits, Physician Profiles, Technician Profiles, and Interpretation Notes utilized in Reporter.

Share Folder: Specifying an optional Share Folder allows for PDF reports and HL7 exports to be stored in an alternate, common location (see Sections 8.10 Reports 8.11 Exports and EHR Integration for detail on those outputs). In order for the reports and exports to be stored in this way, the Share Folder must be specified <u>and</u> the Share option must be set to Yes (if options are set to No, Reports and Exports will be saved under the Private Folder). This feature may be advantageous for enterprise customers with multiple endpoints who wish to have a centralized network location for all generated report or Export files.
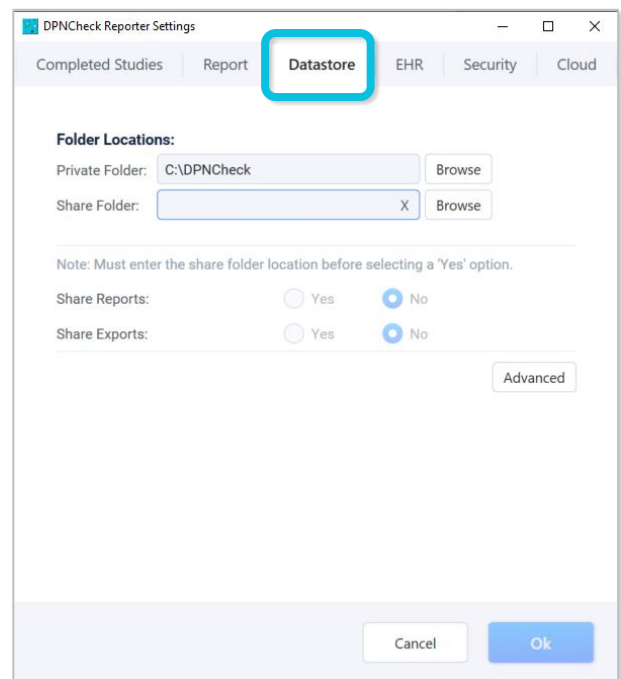
Note: The Private and Share folders specified may not be identical.

Note: Share Reports/Exports will only be available if EHR setting Export Destination is set to "Export to File".

Note: If a Private or Share folder specified does not exist, Reporter will be unable to start. If a Private or Share folder specified becomes inaccessible, Reporter will display the inaccessible path and will not allow the user to proceed until access is available. If the folder is inaccessible at start-up, Reporter will be unable to start.

See Section 15: Appendix E: Using the Same Network Datastore Location
for Multiple Systems for description of the behavior when multiple endpoints point to the same Private and/or
Share Folders.
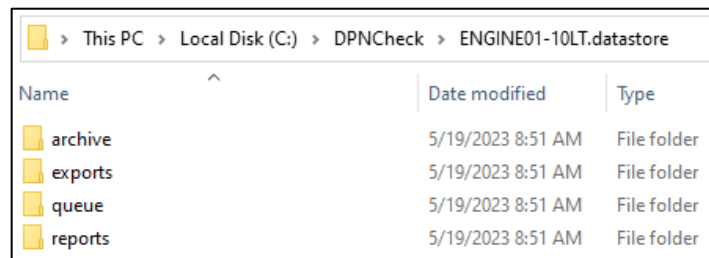
See Section 11 Appendix A: Notes on Network Connection for information on messages related to lost
network connections impacting use of the specified Datastore folders.

8.4.3   Structure of the Datastore Directory

Reporter will create a datastore directory under the private folder (set in Datastore settings) where data
related to individual DPNCheck studies are stored. This datastore directory will be uniquely named based on
the origin PC, using the format "PC Name.datastore", where "PC Name" refers to the name of the endpoint
computer; this allows for use of the same Private Folder by multiple endpoints; see Section 15: Appendix E:
Using the Same Network Datastore Location
for Multiple Systems.

Reporter will also automatically create subfolders within the datastore directory for organizing various types of
files associated with DPNCheck studies:

- The **queue** folder saves study files (in encrypted .nmx format) that will display in the New Studies list
  within Reporter.
- The **archive** folder saves study files (in encrypted .nmx format) that will display in the Completed Studies list within Reporter.
- The **reports** folder contains the PDF reports generated by the user via the "Report" action or via the "Export" action when Export Destination setting is set to "Export to File".

Name	Date modified	Type
archive	5/19/2023 8:51 AM	File folder
exports	5/19/2023 8:51 AM	File folder
queue	5/19/2023 8:51 AM	File folder
reports	5/19/2023 8:51 AM	File folder

> This PC > Local Disk (C:) > DPNCheck > ENGINE01-10LT.datastore

- The **exports** folder contains the HL7 files (base64 encoded) generated by the user via the "Export"
  action when Export Destination setting is set to "Export to File".

Reporter users will need read/write permissions for the Private Folder and Share Folder specified via the
Datastore settings for the endpoint PC that is running Reporter.

Note: It is critical that the datastore folder name structure created by Reporter be preserved.

8.4.4   File naming

Study, report, and export files are named with the following naming convention:

DPN_TimeStamp_ID[PatientID].nmx

The timestamp corresponds to the study date, which is the date and time the first test in a study is uploaded
from the DPNCheck device to Reporter. The timestamp is in the format DDMMYYYYHHMMSS. The Patient ID
included in the filename is what was entered by the user when uploading the test to Reporter.

Manually modifying the Reporter file names is not recommended and may affect the proper function of the
application.

8.5　Normal Limits

Normal Limits allows users to choose how the normal limits are calculated for amplitude and conduction velocity results of the DPNCheck sural nerve conduction tests.

Normal limits are displayed on the Report tab, and an asterisk (*) next to a result for amplitude or conduction velocity indicates if it is abnormal, i.e., below the normal limit. If normal limits are calculated and the Interpretation Guide is selected in Report settings, the results will also be plotted on the Interpretation Guide graphic, as indicated by the gray dot in the image below.
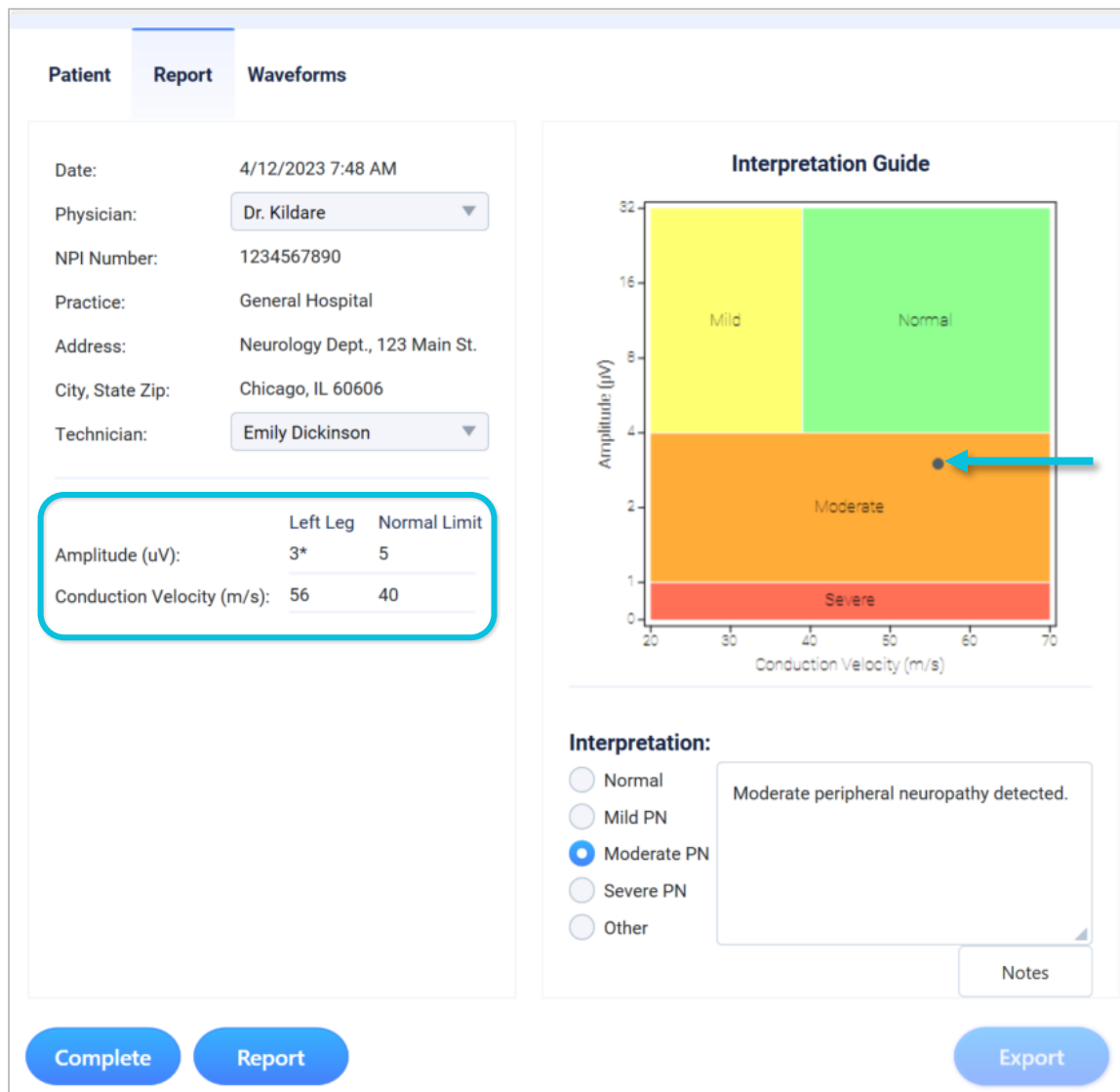
Normal limits may be changed through the Normal Limits setting. It is important to clarify how this setting should be set within your organization prior to installing across the organization, to ensure consistent review of results.
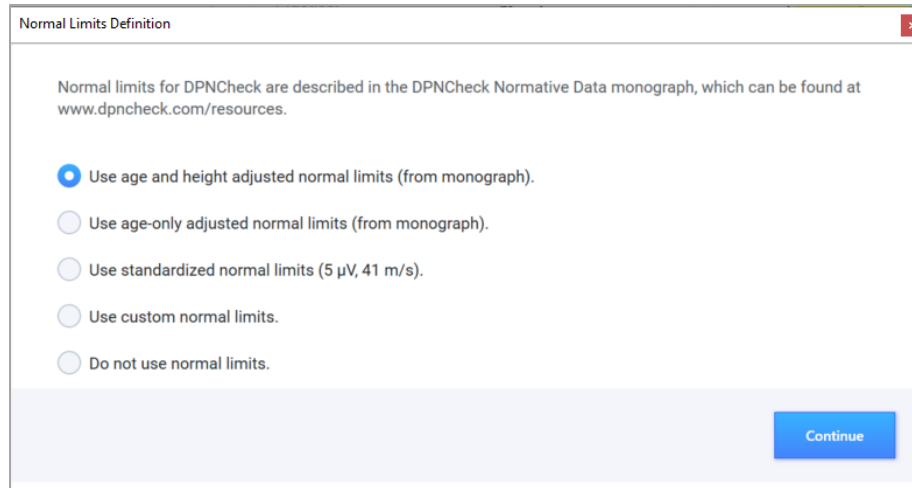
Age and Height adjusted normal limits (from monograph): This is the default selection. If using this Normal Limit setting, age and height must be entered for normal limits to be calculated. The DPNCheck normal limits monograph describes the calculations used for normal limits; visit www.dpncheck.com/resources to view the DPNCheck Normative Data monograph.

Age-Only Adjusted Normal Limits (from monograph): If using this Normal Limit setting, age must be entered for normal limits to be calculated. The height field is not required when using this setting and the height field will not display on the Patient tab. The DPNCheck Normal Limits monograph describes the calculations used for normal limits; visit www.dpncheck.com/resources to view the DPNCheck Normative Data monograph.

Standardized Normal Limits: If using this Normal Limits setting, no demographic entry is required for normal limits to be calculated, and the height field will not display on the Patient Tab. When using this setting, normal limits are set to 5 µV for amplitude and 41 m/s for conduction velocity, therefore <5 µV and <41 m/s are considered abnormal.

Custom Normal Limits: This Normal Limits setting allows the user to specify custom constants and coefficients for use in the calculation of the limits. The DPNCheck Normal Limits monograph describes the equation used for the calculation; visit www.dpncheck.com/resources to view the DPNCheck Normative Data monograph. Upon selecting this Normal Limit setting and selecting **Continue**, the Normal Limit Definitions window will display (shown to the right).

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.**

This option should only be used if alternative normal limits have been obtained using appropriate statistical methods.

Do not use normal Limits: If using this Normal Limits setting, no normal limits will be calculated or displayed.

Note: If the Normal Limits setting does not require height for the limit calculations, the Height field will not display on the Patient tab.

8.6   Temperature Compensation

Temperature compensation is applied by DPNCheck in order to compensate the Conduction Velocity for high or low skin temperatures (see the DPNCheck Device User Manual for further information regarding temperature compensation). Temperature Compensation may be disabled for review of results in Reporter through the Datastore->Advanced settings.

Unless the DPNCheck device is being used in a specific situation where temperature compensation is not desired, this should remain set to Yes.
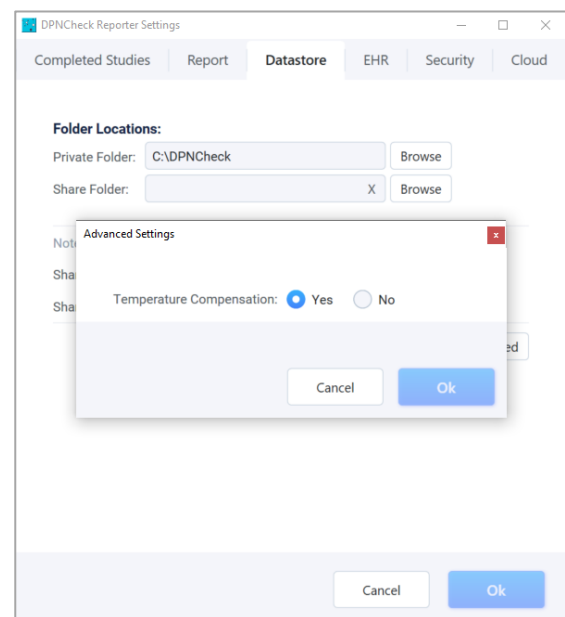
8.7   Physicians

When entering study information, you may select a physician name from the dropdown menu on the Report tab. The contents of the dropdown menu are created within the Physicians setting. Once a physician is selected from the dropdown menu, all information associated with the physician (NPI, practice information) will auto-populate based on the data entered in the physician profile.

If you do not wish to use the practice information fields (Practice Name and Address), you may disable them by removing the selection from "Enable Practice Entry" in the Report settings (Note: the fields will be removed from the Report tab but will still appear in the Physician setting window).

To create a new physician profile, from the Physician settings, click on **+ New Physician**. Enter the associated information for that physician. If you need to enter another physician, click on **+ New Physician** and repeat these steps. If you would like to designate one physician as the default profile, click on the **Default Profile** box when that physician is selected. This physician profile will be automatically populated in the Report tab for a new study. The default physician will be identified in the list with a blue check mark to indicate that it is the default physician. Once you have finished adding physicians, click **Save Changes**. If a physician profile needs to be deleted, click on the desired profile and click **Delete.**

Note: The file containing the physician profiles entered into the application is saved under the private datastore folder (set in Datastore settings). See Section 15: Appendix E: Using the Same Network Datastore Location
for Multiple Systems for detail regarding behavior when using the same network datastore for multiple systems.

8.8   Technicians

When entering study information, you may enter a technician name from the dropdown menu on the Report tab. The contents of the dropdown menu are created within the Technician setting.

To create a new technician profile, from the Technicians setting, click on **+ New Technician** and enter the technician's name. The technician email field is an optional field, and the email address will only appear in the HL7 export. See Section 8.11: Exports and EHR Integration for more information.

If you need to enter another technician, click on **+ New Technician** and repeat these steps. If you would like to save one technician as the default profile, click on the **Default Technician** box. This technician profile will be automatically populated in the Report tab for a new study. The default technician will be identified in the

list with a blue check mark to indicate that it is the default technician. Once you have finished adding technicians, click **Save Changes**.

If a technician profile needs to be deleted, click on the desired profile and click **Delete**.

Note: The file containing the technicians entered into the application is saved under the private datastore folder (set in Datastore settings). See Section 15: Appendix E: Using the Same Network Datastore Location for Multiple Systems for detail regarding behavior when using the same network datastore for multiple systems.

8.9　Interpretation Notes

A library of interpretation notes may be created and stored for efficient entry of the study interpretation when generating the report. The contents of the interpretation notes library are created within the Interpretation Notes setting (accessible through the settings menu or from Report settings). From the Report tab, a note from the library may be added by clicking **Notes** or by right clicking from within the notes window (Note: you must have at least one note in the interpretation notes library in order to do this).

To generate a note, click on **+ New Note** and type the new note in the entry window. When you are finished typing a note, you may either click on **+ New Note** to create another note or click **Save Changes** to save and exit the note library.

To delete a note, click on the note in the library and select **Remove**.

Select **Save Changes** when complete.

If you would like to save this library of interpretation notes to use on other Reporter installations, click on **Export**. You will then be prompted to enter a file name and choose a destination for the file. If you have a file of notes you would like to add to the library, click on **Import**. You will then be prompted to select the desired file from its respective directory.
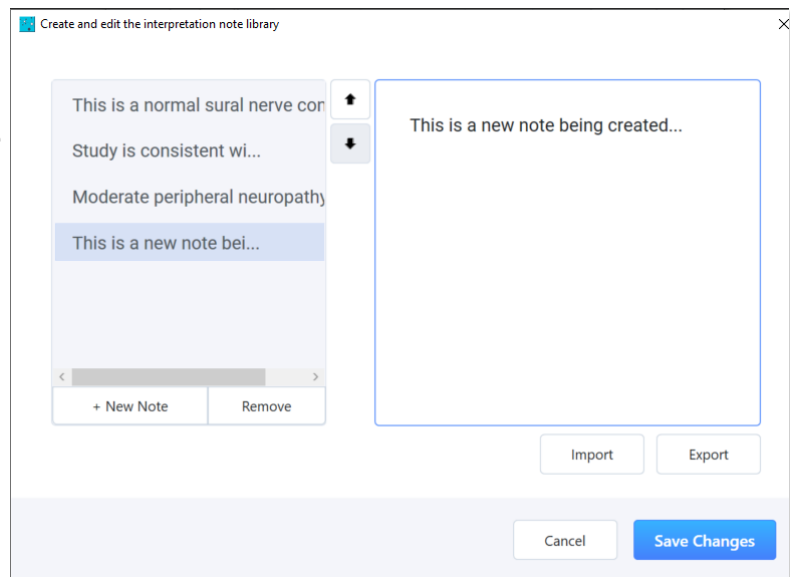
Note: The file containing the interpretation notes entered into the application is saved under the private datastore folder (set in Datastore settings). See Section 15: Appendix E: Using the Same Network Datastore Location
for Multiple Systems for detail regarding behavior when using the same network datastore for multiple systems.

8.10　Reports

Once a study is completed, a report in PDF format may be generated; this creates a summary of results for incorporation into the patient's medical record. Click **Report** to create and open the report in a PDF viewer. You may print the report, and a copy is also saved in your datastore private folder.

If there are multiple tests within the study, the report will display results for the most recent valid test on each limb.

The report is also automatically embedded into the HL7 export if that is generated, see Section 8.11: Exports and EHR Integration.

8.10.1 Report Overview

The report has the following sections:

(1) **Header**: The top section of the report contains the header. The left section of the header displays the Physician, Technician, and Practice Information, as well as the date of the test (date of upload from the DPNCheck device). Inclusion of technician and/or practice information may be enabled or disabled from the Report settings.
The right section of the header displays the patient name, ID, gender, and birth date.

(2) **Results**: The middle section of the report contains the test results. The top left section of the results displays the numeric results of amplitude and conduction velocity, as well as normal limits. Results that are below the normal limits are indicated with an asterisk (*).
The top right section of the results displays the interpretation guide or severity scale, based on the selection made in Report settings. Note that the interpretation guide will only be shown if normal limits have been calculated; required entry of demographic information for normal limits calculation is indicated on the Patient tab with an asterisk (*).
The bottom section of the results displays the waveform(s) recorded by the DPNCheck device. Cursors mark the waveform onset and peaks used in the calculation of the conduction velocity and amplitude results, respectively.

Note on amplitude-only Results: In most cases, the results will contain both amplitude and conduction velocity, as shown in the first report example below. However, as shown in the second report example, in some circumstances, only the amplitude will be shown. In this case, a value of 20m/s is used for plotting the result on the interpretation guide. See Section 8.2 Understanding DPNCheck Results for more information.

(3) **Interpretation and Review**: The bottom section of the report contains the interpretation selected, any entered interpretation notes, and a space for physician signature.

8.10.2 Report Examples

See below for two examples of the report: sample of a right leg test with abnormal results, and sample of a bilateral test with abnormal results.

Sample of a right leg test with abnormal results

Sural Nerve Conduction Study

Dr. Kildare
Technician: Emily Dickinson
General Hospital
Neurology Dept., 123 Main St.
Chicago, IL 60606
Test Date: 4/12/2023 7:48 AM

List of physicians, practice info, and default selection can be created in Settings/Physicians

Include/exclude name of technician performing the test in Settings/Report

Time the study was uploaded to Reporter

Patient Name: Carlos Moreno
Patient ID: 123456789-95
Gender: Male
Birth Date: 6/3/1956

	Right	Normal Limit
Test Date	4/12/2023	
Amplitude (µV)	3*	5
Conduction Velocity (m/s)	56	40

Any result marked with an asterisk indicates that it is below the normal limit

Interpretation Guide
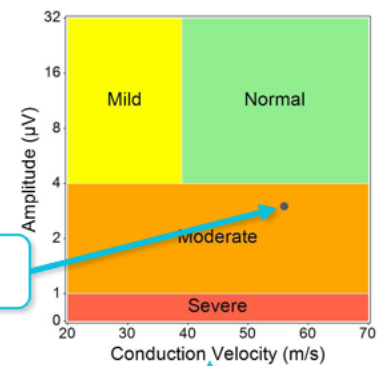
Amplitude and CV values are plotted

This report shows the Interpretation Guide. Other options can be selected in Settings/Report

Right
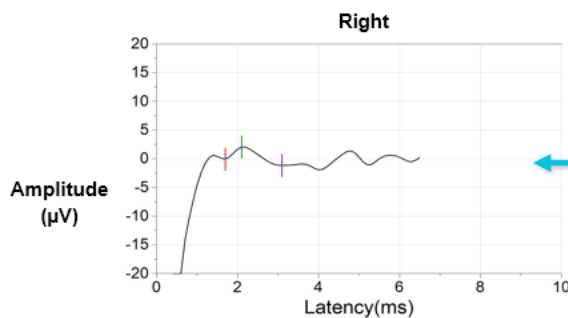
The sural response waveform is displayed here

An interpretation may be selected in the software

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

Moderate peripheral neuropathy detected.

Interpretation Notes may be pre-written for quick selection. The Interpretation Note Library can be created and edited in Settings/Interpretation Notes

Dr. Kildare _____   **Date** _____

Sural Nerve Conduction Study

Dr. Kildare

Technician: Emily Dickinson
General Hospital
Neurology Dept., 123 Main St.
Chicago, IL 60606
Test Date: 6/12/2023 7:48 AM

Patient Name: Carlos Moreno
Patient ID: 123456789-95
Gender: Male
Birth Date: 6/3/1956

	Left	Right	Normal Limit
Test Date	6/12/2023	6/12/2023	
Amplitude (µV)	3*	2*	5
Conduction Velocity(m/s)	39*	--	40

Interpretation Guide

Left and right Amplitude results and left CV result are marked with asterisks indicating that they are below the normal limits

Right results are plotted. Since there was no right CV reported, the right CV is assigned a value of 20m/s for plotting purposes

Right Conduction Velocity was not reported. Use the Amplitude result to determine if right nerve conduction is abnormal

If the CV cannot be recorded, it is noted on the report. Amplitude alone may be used for interpretation

CV and Amplitude values are plotted for the left leg

Left and Right sural response waveforms are displayed

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

Moderate peripheral neuropathy detected.

_____   _____
Dr. Kildare   **Date**

8.10.3 Report Settings

- **Measurement Units**: US (Imperial) or Metric, used for the height entry field in the Patient tab (if shown based on Normal Limit setting). If a change is made to this setting, it will be applied for the next test upload.
  Note: this setting does not affect the PDF report as the height is not displayed on the report.

- **Show**: This selection will set what is shown for interpretation of results based on the normal limits. This is shown both on the Report tab as well as displayed on the PDF report. Severity Scale shows a table for determining neuropathy severity based on whether the amplitude and conduction velocity are normal or abnormal.
  Interpretation Guide, selected by default, will plot the results on a graphic if normal limits are calculated.

- **Date Format**: Select preferred date format from the dropdown list.
- **Time Format**: Select preferred time format from the dropdown list.
- **Document Header**: Displays the default physician and/or practice profile if one is selected within the physicians list. See Section 8.7: Physicians for detail.
  Note: Regardless of the document header displayed in the Report settings, an individual report for the study will always show the physician that has been selected for that study.
- **Include Technician Name**: Selecting this option will include the name of the technician selected on the Report tab on the report.
- **Interpretation Note Library**: This provides access to the interpretation note library for entry, see Section 8.9: Interpretation Notes.

8.11 Exports and EHR Integration

8.11.1 Export and EHR Integration Overview

For completed studies, Reporter can create HL7 exports (compliant with HL7 Standard version 2.3.1) that may be either saved to file or sent to an IP Address for incorporation into the patient's medical record. The HL7 export contains all needed information from the study for integrating into the EHR, including an embedded PDF of the report. See Section 12: Appendix B: Export HL7 Record Format for a full specification of the data included in the export.

8.11.2 EHR Settings

Export Destination

In the EHR Settings, the user can select one of two destination options: Export to File or Export to EHR.

Export to File: This is selected by default. If Export to File is selected, when **Export** is selected for a completed study, an HL7 export file and PDF report file are saved to the designated datastore locations (see Section 8.4: Storing Reporter Studies and Patient Record Outputs for more detail). This HL7 file is saved as a Base64 encoded file.

When an export is performed with Export to File set, the study shown in the Completed Studies list will indicate if successful by blue font a checkmark ✔

Export to EHR: If Export to EHR is selected, when **Send to EHR** is selected for a completed study, an HL7 export is sent via TCP/IP to the IP address and port number specified in EHR Settings.

When the export is performed with Export to EHR set, the study shown in the Completed Studies list will indicate by blue font and message ✔ EHR OK if export is successful. The study will indicate by red font and message ! EHR FAIL if the export is not successful. If the export failed to send to the EHR, the process may be retried by again selecting **Send to EHR**.

Automatic Export

In the EHR settings, the user can enable or disable "Export when Completing Study". If enabled, an export will be performed with the **Complete** action, using the export destination selected in EHR settings. |

8.12 Cloud Data Aggregation

8.12.1 DPNCheck Cloud Overview

The DPNCheck Cloud ("Cloud") is a cloud database that aggregates de-identified DPNCheck data that has been uploaded to the application. The Cloud upload feature is optional and disabled by default. It must be enabled before DPNCheck data is synchronized to the database. The Cloud provides data views and analytics via web accessible dashboards that help care delivery organizations evaluate, monitor, and optimize their peripheral neuropathy screening program.

8.12.2 Cloud Structure and Flow of Data

The structure of the Cloud and the flow of DPNCheck data from the point-of-care to consolidated dashboards is shown in the figure to the right. Following completion of a test with a DPNCheck device, the data is uploaded to Reporter. The user then completes the study by adding patient information, facility information, a study interpretation, and then clicks **Complete**.

If the Reporter application is configured for Cloud upload, then a de-identified subset of the study data is queued for transmission to the Cloud. Queued data is sent to the database whenever the endpoint has an active internet link. New data is synchronized to the Cloud at 1-minute intervals.
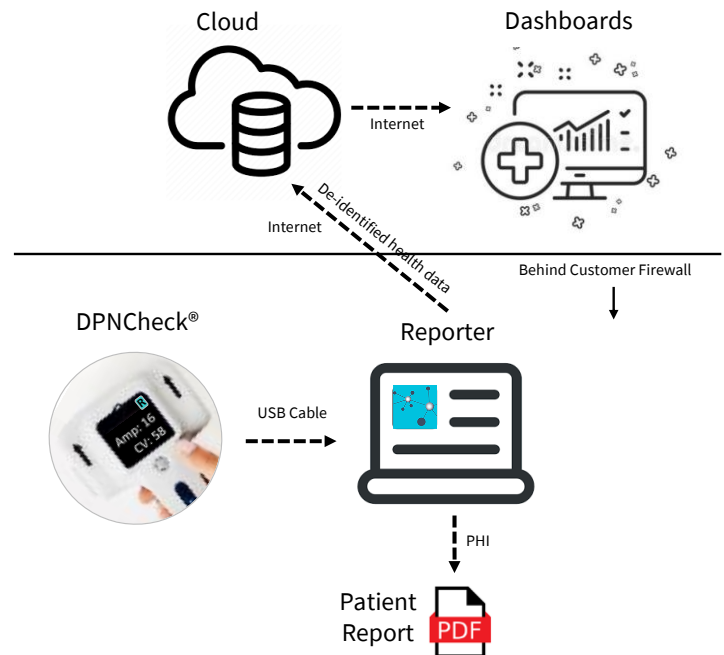
See Section 16: Appendix F: De-identified Data Stored in Cloud for further detail on the de-identified data sent to the Cloud. See Section 9: Security Features and Settings for more information regarding privacy and security of data sent to the Cloud.

Note: Data is only sent to the Cloud for studies completed after the Cloud feature is enabled; previous data is not synchronized.

8.12.3 Dashboard

The data in the Cloud is available via web-based Tableau® dashboards. The dashboards provide three types of information. The first is utilization (i.e., number of tests performed) for a given time period. The second is the rate of abnormal tests for a given time period, including a breakdown by severity. The third type is testing quality which may be used to identify personnel that can benefit from additional training. The data may be viewed at various levels of aggregation or drilled down to individual DPNCheck devices, sites, physicians, or technicians.
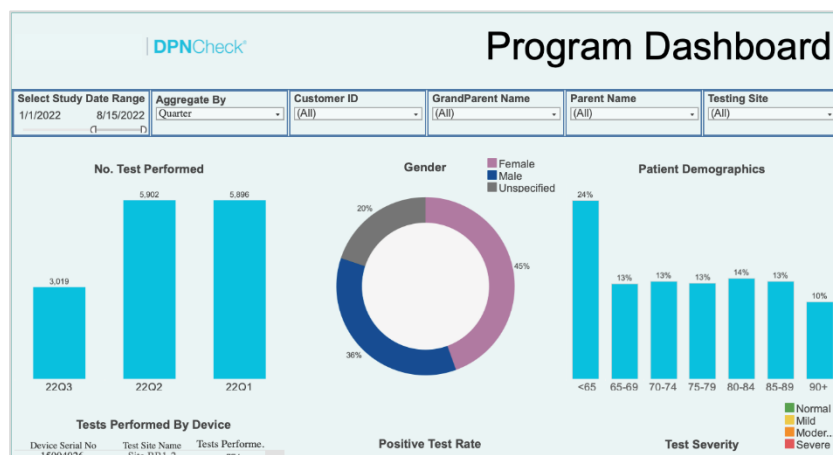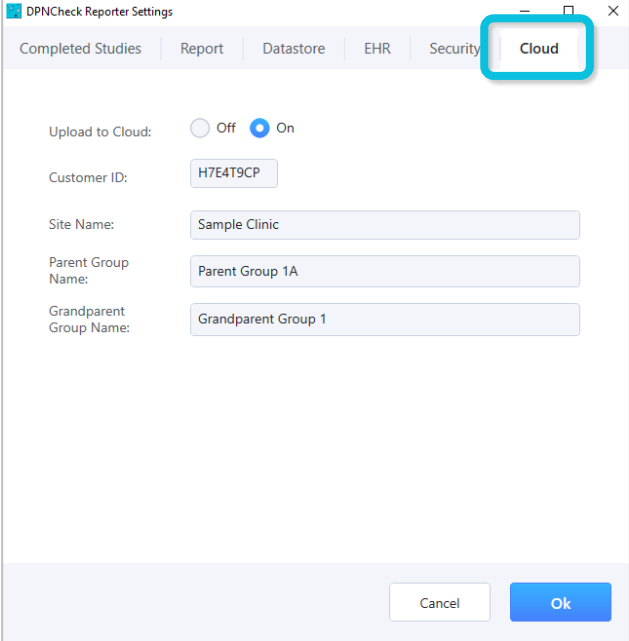
Note: Raw (de-identified) data may be downloaded from the Tableau® Dashboard if desired.

8.12.4 Cloud Settings

Upload to Cloud: This setting enables upload of de-identified study data to the Cloud. It is disabled by default and must be set to "On" to enable Cloud synchronization. If this setting is enabled, then a valid Customer ID must be entered before saving the setting or it will revert to disabled.

Customer ID: This setting designates a unique customer identification (ID) that is provided by DPNCheck The ID is 8 characters in length. Each customer will typically have a single ID under which all its DPNCheck data is aggregated. However, some customers may decide to have multiple IDs such as for organizations that span multiple states where each state has a distinct ID. The dashboards support visualization of data from multiple IDs. Contact the DPNCheck Cloud Administrator (see Section 3: Customer Support Contact) for questions related to Customer IDs and to obtain the initial or additional Customer IDs.

Note that if the Customer ID is changed, previous data will not be reassigned to the new ID; once uploaded, the Customer ID associated with the data is fixed.

Site Name: This is an optional setting that may be used for designating a facility or clinic name for data reporting purposes. The maximum name length is 50 characters.

Parent Group Name: This is an optional setting that may be used for designating a parent group name for data reporting purposes. The maximum name length is 50 characters.

Grandparent Group Name: This is an optional setting that may be used for designating a grandparent group name for data reporting purposes. The maximum name length is 50 characters.

The hierarchical relationship between a customer and the Cloud settings is shown below:
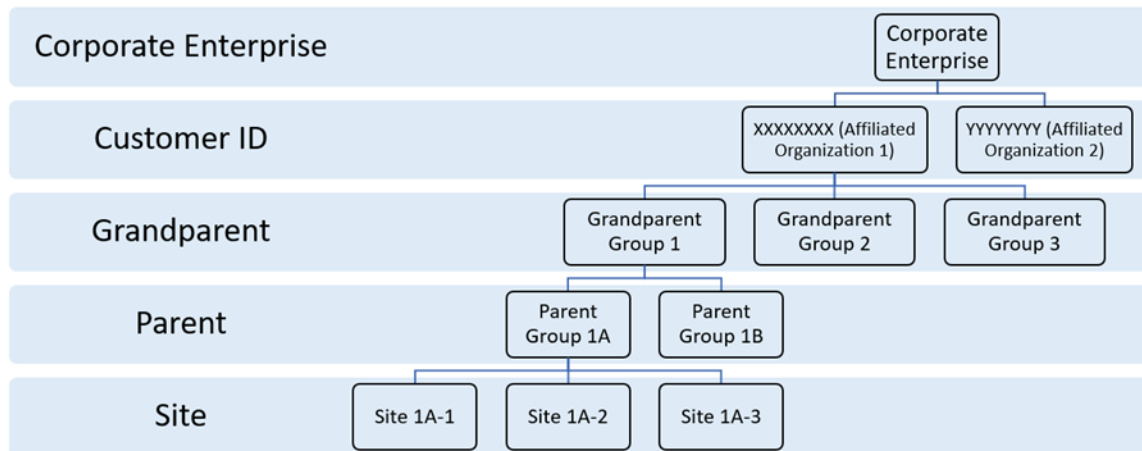
8.13 Study Search

The Studies menu provides various ways to search for a patient study from your New and Completed Studies lists. Search options include:

- By Patient Name
- By Patient ID
- By Physician
- By Technician
- By Practice
- By Date Range
- All Studies
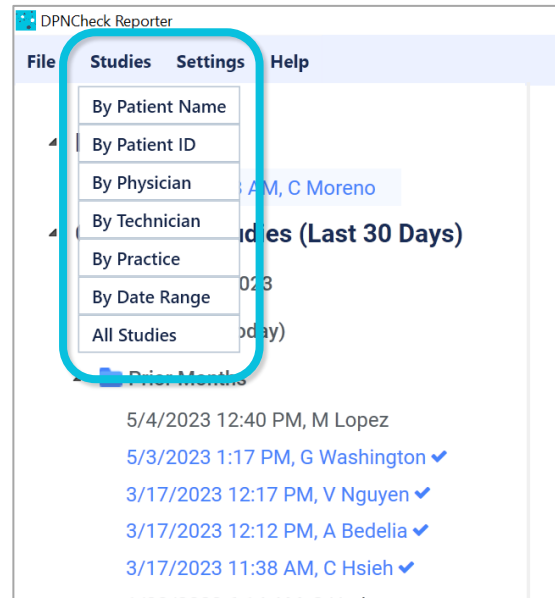
Once a category is selected, a window will open specific to that category. Use the dropdown menu to view the options. Data may be sorted by clicking on any column label.

Note that the completed studies included in the study search will be dependent upon the time period selected for the Completed Studies setting. See Section 8.1.6 Customizing Your Study View.

9   Security Features and Settings

9.1   Adherence to Microsoft Windows Best Practices

The Reporter Application is a Microsoft Windows based desktop application with multiple Security features. Reporter is designed to run in a Windows 10+ environment. It has no networking (LAN/WAN) configuration dependencies.

Reporter adheres to the following MS Best Practices for Desktop Applications:

- Adheres to Windows Security Best Practices
- Windows Attack Surfaces are not exposed by verifying that ACLs and Services are implemented in a way that does not put the Windows system at risk.
- Supports Windows security features
- Adheres to system restart manager messages
- Supports a clean, reversible installation
- Digitally signs files and drivers
- Does not block installation or app launch based on an operation system version check
- Does not load services or drivers in safe mode
- Allows User Account Control guidelines
- Installs to the correct folders by default
- Supports multi-user sessions
- Supports x32 and x64 versions of Windows

9.2   Data Transfer from DPNCheck Device

The transfer between the DPNCheck device and Reporter is secure via a USB cable connection; no data is exposed during this transfer via a network connection. The unmapped raw data exchanged between the DPNCheck device and Reporter contains no patient identifiable data. There is no external sharing of data.

9.3   Storage of PHI/PII

Reporter contains the following PHI/PII:

1. Patient ID: Patient ID is a required field for identification of a DPNCheck study/test. Typically, the Medical Record Number is used for Patient ID.
2. Patient First Name: This is an optional field, but if entered, is then included in the report and export (artifacts created for incorporation into the patient medical record).
3. Patient Last Name: This is an optional field, but if entered, is then included in the report and export (artifacts created for incorporation into the patient medical record).
4. Patient Birth Date: This is entered for calculation of normal limits of the DPNCheck test result.
5. Patient Height: This is entered for calculation of normal limits of the DPNCheck test result.
6. Patient Gender: The selections are male, female, and unspecified (selected by default).
7. DPNCheck test results: This includes the amplitude, conduction Velocity, and waveform from the DPNCheck sural nerve conduction test.
8. DPNCheck test Interpretation: These are optional fields and include a selected interpretation category and entered notes.

For detailed information regarding all locations of PHI/PII and options for controlling exposure, please contact DPNCheck (see Section 3 Customer Support Contact).

9.4   Application Digital Signature

DPNCheck code signing certificate is verified via Certificate Authority (CA)- Comodo Inc.

Each DPNCheck Reporter DLL, EXE, LIB is digitally signed with the DPNCheck signature which ensures that each can be verified as valid by the CA authority. All virus scan software and the Windows OS verify authenticity using the CA. This proves that the software is from a published and known Vendor and that the code has not been altered since the Publisher (DPNCheck) signed the code. Software not digitally signed can be blocked by anti-virus software and/or deemed unsafe to uninstall.

9.5   Optional User Login for Reporter Software

Reporter supports the standard MS Windows user identification and password login, reducing risk of unauthorized users accessing and running Reporter.

User Login Security can be enabled in Security settings. If selected, the user will be required to enter their Windows user identification and password login to access Reporter.

Reporter shall authenticate the credentials to either the Windows Local Workgroup login or to the Domain Login. When entering credentials, the user will be given 3 attempts for correct entry. After 3 failed attempts, the software shall display a message to contact "your local administrator" for assistance.

Note: DPNCheck has an unlock utility available; see next section.
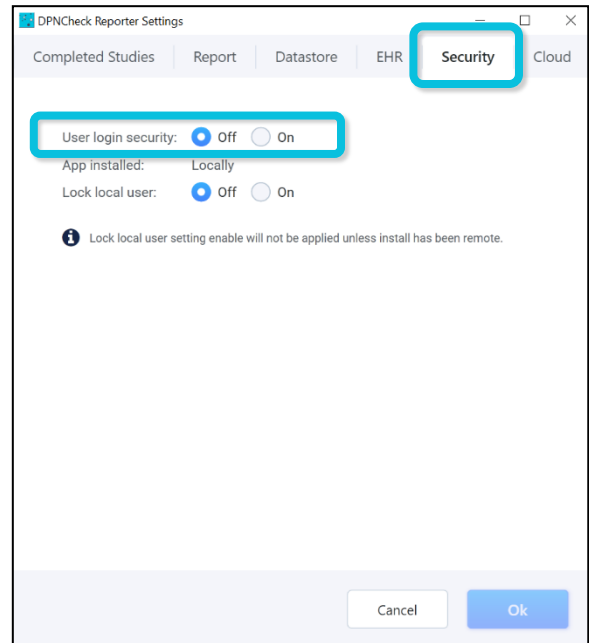
Note: The Reporter application has no knowledge of the credentials entered by the user when User login security is enabled and does not store them. The application uses the Microsoft Windows authentication service to determine if the credentials provided by the user (when opening the application) are a valid user account. The Microsoft Windows Server operating system implements the Kerberos version 5 authentication protocol and extensions for public key authentication.

9.6   Unlock Utility

A utility is provided for use in the event that a user has been locked out of the application. As described in the previous section, if the Security setting "User login security" has been enabled, the user is required to enter their Windows credentials to use Reporter. A user will be locked out following 3 consecutive failed login attempts. This utility is provided as part of the installation packages.

9.7   Locked Settings

A remote install setting option will prevent the end user from changing specific settings. This will be set by IT via the Security settings prior to executing a remote install.

A list of lockable settings can be found in Section 13: Appendix C: Reporter Applications Settings Summary. The procedure for locking settings may be found in Section 14.4 Settings & Process for using Lock settings.
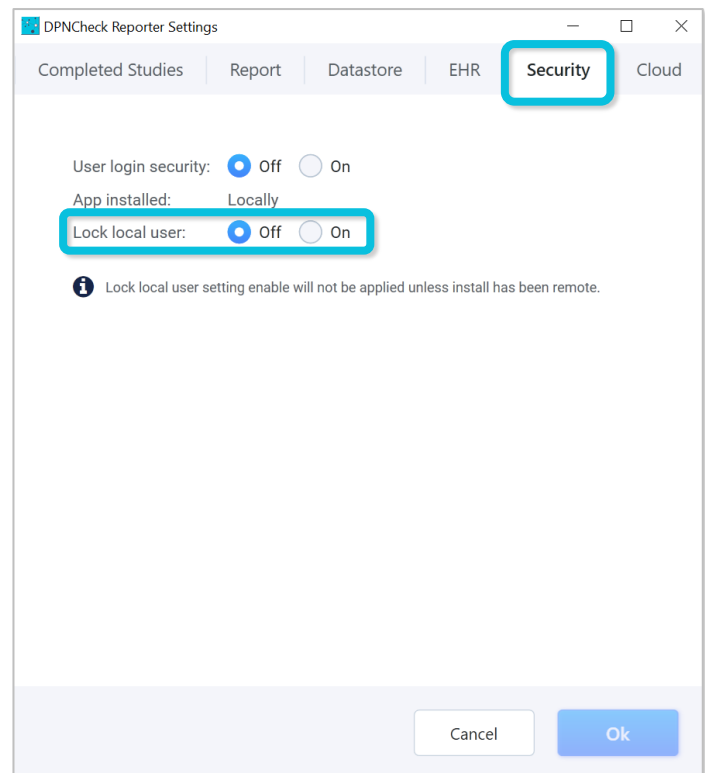
9.8   Reporter UNC Path Security

Reporter supports setting datastore locations using a hardened UNC path. This policy setting configures secure access to UNC paths. IT can enable a policy allowing Windows only access to the specified UNC paths after fulfilling additional security requirements. See Section 8.4.2: Datastore Setting, Private and Share Folders for details on datastore.

9.9   File Protection

Reporter uses AES256 encryption for study files, and a Base64 binary-to-text encoding scheme for HL7 export files saved to the datastore folder(s). No report or export files are saved to datastore when exporting using the Export to EHR destination.

9.10   Event Logging

DPNCheck Reporter writes log messages for various events that occur during use. The log messages are intended to provide an audit trail for the use of Reporter to show who is accessing, editing, and performing actions related to the DPNCheck test results and patient data, as well as in error reporting (e.g., network loss) for assistance in troubleshooting.

9.10.1 Log Descriptions

Two types of logs may be generated, one Internal Log, which contains Personally Identifiable Information (PII), and a second Support Log which has PII redacted. By default, only the Support logs (redacted PII) are written. Internal and Support logs contain the same types of log events, but for the Support log, redaction of PII is performed by either substituting the Patient ID with a timestamp of the study, or by obscuring the PII with "@" symbols.

The general types of event logs created in the log files are as follows:

- Application start-up information
- Device connection and test import
- Viewing, editing, completing studies
- Settings changes
- Network connection loss/datastore path access issues
- Generation of report and export
- User login fail attempts, use of unlock utility

Messages contain the following information for identification:

- PC Name
- Timestamp of the log
- Domain and Username
- Study timestamp (when uploaded from the device) and Patient ID are used to identify logs related to particular studies (in the Support log with redacted PHI, only the timestamp is used)

9.10.2 Integration with Microsoft Eventlog

Reporter supports writing of events to the Microsoft Eventlog. To enable this, DPNCheck Reporter must be registered as a source with Microsoft Eventlog. By default, the Support log messages are written to Microsoft Eventlog.

9.10.3 Logging Customization

There are multiple options for customizing use of Internal and Support logs and log location. Contact DPNCheck (see Section 3 Customer Support Contact) for further assistance if the default configuration does not suit your organization's needs.

9.11 Cloud Privacy and Data Security

9.11.1 Patient Privacy

The Cloud holds de-identified health data as defined in 45 CFR §164.514(a-b), the HIPAA Privacy Rule. The HIPAA regulation provides two ways that heath information can be judged as de-identified: expert determination and safe harbor. In the present case, the expert method was used. The assessment was conducted according to the standard set forth in 45 CFR §164.514(b) for statistical de-identification of information. The data sent from Reporter and stored in the Cloud is described in Section 16: Appendix F: De-identified Data Stored in Cloud.

Because the data uploaded from Reporter to the Cloud is de-identified, the storage of this information in a cloud database server managed by a partnering organization (i.e., DPNCheck, Inc.) is not subject to HIPAA regulations. It is not necessary to establish a Business Associate Agreement; the service is covered by the DPNCheck Cloud License Agreement (see www.dpncheck.com/reporter2-3eula/).

9.11.2 Data Security Systems and Processes

All data uploaded to the Cloud are tagged with a unique customer identification (ID) code that consists of 8 alphanumeric characters. The customer ID is provided by DPNCheck.

Communication between the Reporter application and the Cloud is performed via HTTPS. The Cloud is hosted on Amazon Web Services (AWS) which is a secure cloud computing environment. The Cloud database

is managed through Heroku Postgres which is a secure database service. A SQLite database containing deidentified record information is stored locally on the PC; this is only utilized if the Cloud functionality is enabled.

Dashboards are hosted on the Tableau Server and access to an organization's data is governed through the Tableau Row Level Security scheme. Access to dashboards is controlled by customer login credentials that are provided by DPNCheck. To obtain access to Cloud dashboards contact the DPNCheck Cloud administrator (see Section 3: Customer Support Contact).

For more information about Tableau Server Platform Security, visit htts://www.tableau.com/enterprise-it/security. For a description on Tableau Row-Level Security, visit https://help.tableau.com/v2021.4/server/en-us/rls_options_overview.htm.

10 Safety, Service, FDA Notification and License Agreements

10.1 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.

10.2 Service

Should any aspect of the Reporter Software require service, contact DPNCheck Customer Support at 844.DPN.CHECK (844.376.2432)

10.3 FDA Notification

The Reporter 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 DPNCheck, 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, DPNcheck should be notified of any device failures or malfunctions. Issues encountered should be reported to the DPNCheck Customer Support department at 844.DPN.CHECK (844.376.2432). Outside of the United States, problems should be reported to the nearest DPNCheck distributor. This information will help ensure that DPNCheck continues to provide products and services of the highest possible quality.

10.4 DPNCheck® Reporter End-User License Agreements

See www.dpncheck.com/reporter2-3eula/ for full text of the DPNCheck Reporter End-User License Agreement and the DPNCheck Reporter Cloud End User License Agreement.

11 Appendix A: Notes on Network Connection

Use of the Reporter Software requires connectivity to all folders specified in Datastore settings and read/write capability. The folders should be on a network drive where bandwidth to support the connection is available during the hours of use by the end users.

If connection to any of the folders is not available, the following messages will display:

At Reporter startup, if the private and/or shared folder is on a network drive, and the network path is unavailable, Reporter will not open, and the following message will display:
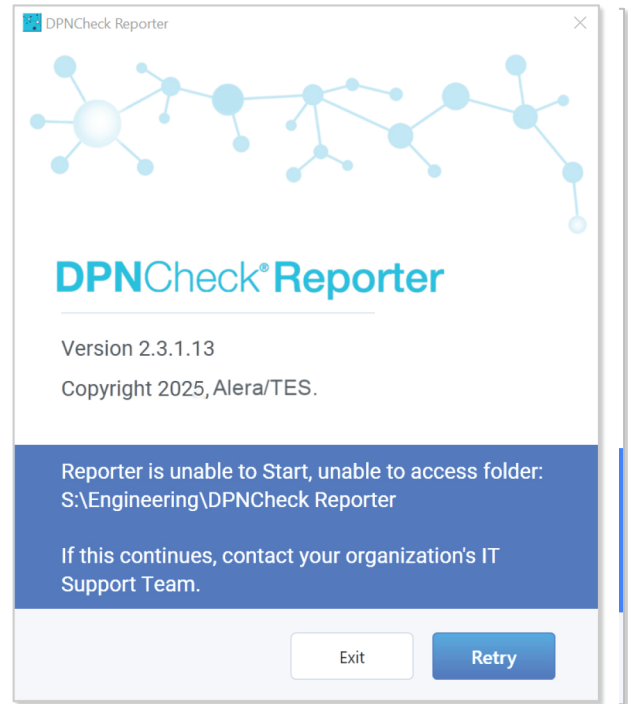
- If at any time during use of Reporter, the connection to the network path is interrupted, the following message will display alerting user of connectivity status:
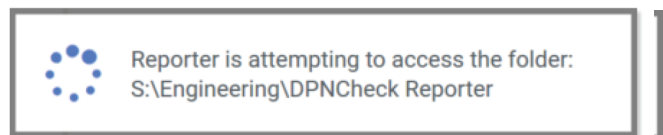
- If the network connection is not restored after a period of time, the following message will display:
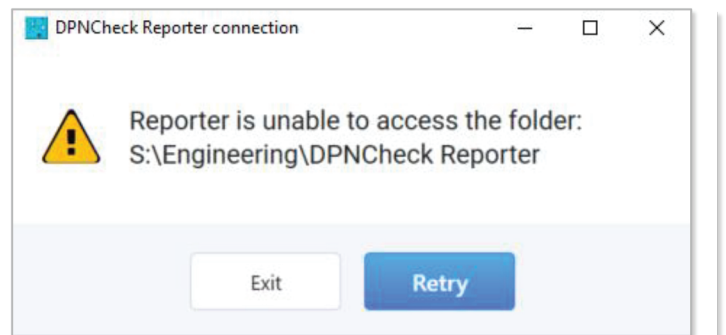
12 Appendix B: Export HL7 Record Format

The Reporter HL7 Export Message consists of the following segments, following HL7 standard version 2.3.1:

Segment	Index	Purpose
MSH	N/A	Required segment
PID	1	Patient information
OBR	1	Standard observation request segment
NTE	1	Results narrative
NTE	2	Normal limits type
NTE	3	Interpretation guide
NTE	4	Clinician interpretation and notes from Reporter
NTE	5	Source trace information
OBX	1-4	Up to four result segments
OBX	Next OBX index	PDF file

MSH Segment	
Field	**Value**
MSH.1-Field Separator [ST]	|
MSH.2-Encoding Characters [ST]	^~\&
MSH.3-Sending Application [HD]	DPNCheck Reporter
MSH.7-Date/Time Of Message [TS]	Timestamp of export (YYYYMMDDHHMMSS)
MSH.9-Message Type [MSG]	
MSH.9.1-Message Code	ORU
MSH.9.2-Trigger Event	R01
MSH.11-Processing ID [PT]	P
MSH.12-Version ID [VID]	2.3.1
MSH.18-Character Set [ID]	UNICODE

PID Segment	
Field	**Value**
PID.1-Set ID - PID [SI]	1
PID.3-Patient Identifier List	
PID.3.1-Id Number [ST]	Patient ID
PID.3.5-Identifier Type Code [ID]	MR
PID.5-Patient Name [XPN]	
PID.5.1-Family Name [FN]	Patient Last Name
PID.5.2-Given Name [ST]	Patient First Name
PID.7-Date/Time of Birth [TS]	Patient Birthdate (YYYYMMDD)
PID.8-Administrative Sex [IS]	F, M, O, U

OBR Segment	
Field	**Value**
OBR.1-Set ID - OBR [SI]	1
OBR.7-Observation Date/Time [TS]	Timestamp of first upload in report (YYYYMMDDHHMMSS)
OBR.16-Ordering Provider [XCN]	
OBR.16.1-ID Number [ST]	NPI Number
OBR.16.2-Family Name [FN]	Physician Name
OBR.16.13-Identifier Type Code [ID]	NPI
OBR.16.14-Assigning Facility [HD]	Practice Name
OBR.25-Result Status [ID]	F
OBR.34-Technician [NDL]	
OBR.34.1-Name [CN]	
OBR.34.1.2-Family Name [ST]	Technician Name (complete name as stored by Reporter)

NTE Segment: Test Results Narrative	
Field	**Value**
NTE.1-Set ID - NTE [SI]	1
NTE.2-Source of Comment [ID]	L
NTE.3-Comment [FT]	Results Narrative (see below)

Results Narrative
Statement 1: "DPNCheck sural nerve conduction test results."
Statement 2: "The {left|right}{amplitude|conduction velocity} was {normal|outside normal limits}."
Statement 3: The {left|right} response was undetectable.

Example: DPNCheck sural nerve conduction test results. The left amplitude was normal. The left conduction velocity was normal.

NTE Segment – Normal Limits Type	
Field	**Value**
NTE.1-Set ID - NTE [SI]	2
NTE.2-Source of Comment [ID]	L
NTE.3-Comment [FT]	Normal Limits Source (see below)

Normal Limits Type
"Normal Limits Type: {generic|age and height corrected|age corrected|height corrected|no normal limits applied}."

NTE Segment – Interpretation Guide	
Field	**Value**
NTE.1-Set ID - NTE [SI]	3
NTE.2-Source of Comment [ID]	L
NTE.3-Comment [FT]	Interpretation Guide (see below)

Interpretation Guide

"Peripheral Neuropathy Interpretation Guide (informational purposes only). NORMAL: both amplitude and conduction velocity normal. MILD: conduction velocity outside normal limits with normal amplitude. MODERATE: amplitude outside normal limits. SEVERE: undetectable response."

NTE Segment – Interpretation Notes	
Field	**Value**
NTE.1-Set ID - NTE [SI]	4
NTE.2-Source of Comment [ID]	L
NTE.3-Comment [FT]	Interpretation Notes (see below)

Interpretation Notes

"Selected Interpretation: {Normal|Mild peripheral neuropathy|Moderate peripheral neuropathy|Severe peripheral neuropathy|Other|Not Provided}. Interpretation Notes: {interpretation notes from Report Tab}."

NTE Segment – Trace Information	
Field	**Value**
NTE.1-Set ID - NTE [SI]	5
NTE.2-Source of Comment [ID]	L
NTE.3-Comment [FT]	

Trace

"Trace information. Technician: {Technician Name, Technician Email}. System Name: {System Name}. Local Domain/User Name: {Local Domain/User Name}."

OBX Segments	
Up to 4 OBX segments transmit the actual nerve conduction values.	
Field	**Value**
OBX.1-Set ID - OBX [SI]	1,2,3,4
OBX.2-Value Type [ID]	NM
OBX.3-Observation Identifier [CE]	
OBX.3.1-Identifier [ST]	DPNCheck-{Left, Right}
OBX.3.2-Text [ST]	DPNCheck-{Left, Right}
OBX.3.3-Name of Coding System [ID]	L
OBX.5-Observation Value [Varies]	Result
OBX.6-Units [CE]	microvolts (amplitude), meters/second (conduction velocity)
OBX.7-References Range [ST]	>4, >40 (examples)
OBX.8-Abnormal Flags [ID]	L (if below normal limit, including undetectable), empty if normal value
OBX.11-Observation Result Status [ID]	F
OBX.14-Date/Time of Observation [TS]	Timestamp (data uploaded)

OBX Segment – PDF File (Base 64 encoded)	
Field	**Value**
OBX.1-Set ID - OBX [SI]	next consecutive value in OBX sequence
OBX.2-Value Type [ID]	ED
OBX.3-Observation Identifier [CE]*	
OBX.3.1-Identifier [ST]	DPNCheck Report
OBX.5-Observation Value [Varies]	DPNCheck Reporter^AP^PDF^Base64^[PDF DATA]

Reporter Generated HL7 Example Message
MSH|^~\&|DPNCheck Reporter||||20230110142641||ORU^R01||P|2.3.1||||||UNICODE
PID|1||10000005^^^^MR||Smith^Timothy||19950517|M
OBR|1||||||20230110133005|||||||||||1234567980^Selma
Furguson^^^^^^^^^^NPI^TestPractice||||||||||F||||||||||&Sally Rutherford
NTE|1|L|DPNCheck sural nerve conduction test results. The left amplitude was normal. The left conduction velocity was normal. The right amplitude was normal. The right amplitude was outside normal limits.
NTE|2|L|Normal Limits Type: age and height corrected.
NTE|3|L|Peripheral Neuropathy Interpretation Guide (informational purposes only). NORMAL: both amplitude and conduction velocity normal. MILD: conduction velocity outside normal limits with normal amplitude. MODERATE: amplitude outside normal limits. SEVERE: undetectable response.
NTE|4|L|Selected Interpretation: Mild peripheral neuropathy. Interpretation Notes: Recheck in 1 year.
NTE|5|L|Trace information. Technician: Sally Rutherford, sallyr@mailmail.com. System Name: BOETTCHER-10DT. Local Domain/User Name: DPNCheck /BBoettcher.
OBX|1|NM|DPNCheck-Left^DPNCheck-Left^L||16|microvolts|>8||| |F|||20230110133204
OBX|2|NM|DPNCheck-Left^DPNCheck-Left^L||49|meters/second|>48||||F|||20230110133204
OBX|3|NM|DPNCheck-Right^DPNCheck-Right^L||13|microvolts|>8||||F|||20230110133005
OBX|4|NM|DPNCheck-Right^DPNCheck-Right^L||48|meters/second|>48|L |||F|||20230110133005
OBX|5|ED|DPNCheck Report||DPNCheck Reporter^AP^PDF^Base64^

13 Appendix C: Reporter Applications Settings Summary

13.1 Settings Descriptions

Completed Studies Settings Tab		
Setting	**Description/Options**	**Can Lock?**
Completed Studies	Controls the time period of Completed Studies loaded/shown in the Studies list and study search. (This setting only affects the display of date ranges. All studies will still be retrievable, even if not visible in the list). Options: All Available, Last 10 Days, Last 30 Days (Default)	NO

Report Settings Tab		
Setting	**Description/Options**	**Can Lock?**
Measurement (US or Metric)	Allows user to select units for height entry (height field entry dependent on Normal Limits setting) Options: US (Default if Operating System Language is US English), Metric	YES
Show	Controls what is shown related to interpretation based on Normal Limits. Options: Severity Scale, Interpretation Guide (Default), Neither	YES
Date Format	Allows user to select the desired format for Date shown in Study List, Report tab, Waveforms Tab, and Report. Options: General Windows options for date format, default = M/DD/YYYY	NO
Time Format	Allows user to select the desired format for Time shown in Study List, Report tab, Waveforms Tab, and Report. Options: General Windows options for time format, default = H:MM AM/PM	NO
Document Header	Displays the Physician Profile that will be automatically populated in the Report tab for new studies, when a Default Physician Profile has been selected in Physician Settings. No settings control on this tab.	NO
Enable Practice Entry	Determines whether certain fields for Practice Information associated with the Physician are shown on the Report Tab for entry and Report. Applies to the following Practice fields: Practice Name and Address fields. Options: Enabled (Default), Disabled	YES
Include Technician Name in PDF Report	Determines whether the Technician Name entered on the Report tab will be included in the header of the PDF Report. Options: Enabled, Disabled (Default)	YES
Interpretation Note Library	Provides access to the Interpretation Notes Library from this tab. No settings control on this tab.	NO

Datastore Settings Tab		
Setting	**Description/Options**	**Can Lock?**
Private Folder	Sets the path for storing study (AES 256 encrypted .nmx), report (PDF), and export (base 64 encoded HL7) files, as well as physicians and technicians lists, normal limits setting, and interpretation notes. May be a UNC path. Default: C:\DPNCheck	YES
Share Folder	Optional. Sets the path for sharing Report (PDF) and Export (base 64 encoded HL7) files if Export Destination setting set to Export to File. May be a UNC path. Default: No path specified by default.	YES
Share Reports	Controls sharing of Report (PDF) files. If enabled, Report files are saved to the Share Folder specified; if disabled, they are saved to the Private Folder. Setting is active if Export Destination setting set to Export to File. Options: Yes, No (Default)	YES
Share Exports	Controls sharing of Export (base 64 encoded HL7) files. If enabled, Export files are saved to the Share Folder specified; if disabled, they are saved to the Private Folder. Setting is active if Export Destination setting set to Export to File. Options: Yes, No (Default)	YES
Advanced		
Temperature Compensation	Controls use of temperature compensation to the Conduction Velocity results in a study. Unless the DPNCheck device is being used in a specific situation where temperature compensation is not desired, this should remain set to Yes. Options: Yes (Default), No	YES

EHR Settings Tab		
Setting	**Description/Options**	**Can Lock?**
Export Destination	Controls the destination for sending the HL7 Export. "Export to HL7 File" will save base64 encoded HL7 exports to the specified Datastore folder. "Export to EHR" will send the base64 encoded HL7 to an HL7 MLLP receiver via TCP/IP to a specified IP Address and Port Number. Options: Export to File (Default), Export to EHR	YES
Automatic Export	When enabled, upon selecting the Complete button to Complete a study, an Export will also be performed simultaneously, sent to the destination specified in the Export Destination setting. Options: Yes, No (Default)	YES

Security Settings Tab		
Setting	Description/Options	Can Lock?
User login security	When enabled, user must enter Windows credentials in order to login to the Reporter application. See Section 13.2 Settings Locations below related to setting this to "On" during the remote install process. Options: Off (Default), On	YES
Lock local user	Controls locking of the group of settings that may be locked if the application is installed Remotely. See Section 14.4 Settings & Process for using Lock settings for instructions on how to use this setting during the remote install process. Options: Off (Default), On	YES

Cloud Settings Tab		
Setting	Description/Options	Can Lock?
Upload to Cloud	Controls the use of the Cloud upload feature to upload de-identified Reporter study data to the DPNCheck cloud upon study Complete action. Requires an active Internet connection. Setting will not be saved if a Customer ID is not entered. Options: Off (Default), On	YES
Customer ID	ID is assigned by DPNCheck and associates the de-identified data with your organization.	YES
Site Name	This is an optional setting that may be used for designating a facility or clinic name for data reporting purposes.	YES
Parent Group Name	This is an optional setting that may be used for designating a parent group name for data reporting purposes.	YES
Grandparent Group Name	This is an optional setting that may be used for designating a grandparent group name for data reporting purposes.	YES

Normal Limits Setting		
Setting	Description/Options	Can Lock?
Normal Limits	Controls which normal limits calculation will be applied for the amplitude and conduction velocity results of a study. Options: Use age and height adjusted normal limits (Default) Use age only adjusted normal limits Use standardized normal limits Use custom normal limits Do not use normal limits	YES

Interpretation Notes		
Setting	Description/Options	Can Lock?
Interpretation Notes	Optional. Creates a library of notes for efficient entry of study interpretation. User may create as many notes as needed.	NO

Physicians		
Setting	**Description/Options**	**Can Lock?**
Physicians	Optional. Creates a set of Physician Profiles that may be selected on the Report tab, containing the following fields: Physician (required), NPI Number (optional), Practice Name (optional), Address 1 (optional), Address 2 (optional), City, State, Zip (Optional). If a default is selected, this Physician will be auto-populated in the Report tab for each new study.	NO

Technicians		
Setting	**Description/Options**	**Can Lock?**
Technicians	Optional. Creates a set of Technicians that may be selected from the Report tab, containing the following fields: Technician Name (required), Technician Email (optional). If a default is selected, this Technician will be auto-populated in the Report tab for each new study.	NO

13.2 Settings Locations

Reporter stores settings in the following files and locations:

File and Location	Settings Contained
SLReporterStng.xml, in C:\DPNCheck	Completed Studies Measure (US or Metric) Show (Severity scale, Interpretation Guide, neither) Date Format Time Format Enable Practice Entry Include Technician Name in PDF Report Private Folder* Share Folder* Share Reporter Share Exports Temperature Compensation Export Destination Automatic Export Lock Local User Upload to Cloud Customer ID* Site Name* Parent Group Name* Grandparent Group Name*
NMXSecure.config in C:\Users\[USER]\AppData \ Local\DPNCheck,_Inc	User Login Security *Note*: For a Remote Install, to set this setting to non-default value (i.e., enabled), copy the NMXSecure.config file into the respective C:\users folder shown on the left. For User Login Security to be the non-default value, the following key must be set in the config file: "IsUserSecurityOn"…<value>True</value>
LowerLimitsNormal.xml in Private Folder	Normal Limits
DPNCheckReporterNotes.xml in Private Folder	Interpretation Note Library*
phyprofiles.xml in Private Folder	Physicians List* *Note*: List must be created from within Reporter; Reporter assigns a unique ID in the phyprofiles.xml file to each profile (for internal Reporter use only, IDs should not be modified).
technicians.xml in Private Folder	Technicians List* *Note*: List must be created from within Reporter; Reporter assigns a unique ID in the technicians.xml file to each profile (for internal Reporter use only, IDs should not be modified).

*Depending on how your organization decides to use these settings, they may differ among endpoint Reporter instances (for example, your organization may wish to have different Physician lists accessible from different PCs). This needs to be considered when setting up Remote Installation.

See Section 14.4 Settings & Process for using Lock settings below for instruction on locking settings during the Remote Installation process.

14 Appendix D: Remote Installation Notes and Examples

As described in Section 7.5: Installation Guide – Remote/Silent Installation, a remote installation process may be used to silently push the Reporter application to multiple endpoints. This Appendix includes examples for the remote installation as well as some detailed notes on set up.

14.1 Overview of Remote Installation Package Files

Name	Date modified	Type	Size
Documentation	5/11/2023 5:51 PM	File folder	
ExampleInstallScripts	5/16/2023 3:15 PM	File folder	
ExampleReporterConfigFiles	5/14/2023 9:03 AM	File folder	
Tools	5/11/2023 5:59 PM	File folder	
setup.exe	5/9/2023 11:32 AM	Application	621 KB
SL.COM.Setup.msi	5/9/2023 11:32 AM	Windows Installer ...	15,006 KB

Example Installation Scripts: There are multiple .bat file examples provided to show your IT organization what is needed for creating their own remote installation using preferred 3rd party tools and scripts.

Tool, DPNCheckUnlock.exe: This is a tool that may be used by IT in the case where the Security setting "User login security" has been enabled and the user has become locked out of the application due to incorrect password entry. See Section 9.6: Unlock Utility. Note that this file is provided to IT for use with the User login security setting and should not be included as part of the Remote Install package created for the remote installation process to your endpoints.

Example Reporter Configuration Files: Sample .xml files for the Normal Limits (LowerLimitsNormal.xml), Settings (SLReporterStng.xml), Physicians (phyprofiles.xml), and Technicians (technicians.xml) are used in conjunction with the .bat files to demonstrate how these work together for remote installation. This is not the full set of files that may be needed in the remote installation process, see Section 13.2: Settings Locations for further detail.

Application Installer files: setup.exe and SL.COM.Setup.msi files installation executables required for installation.
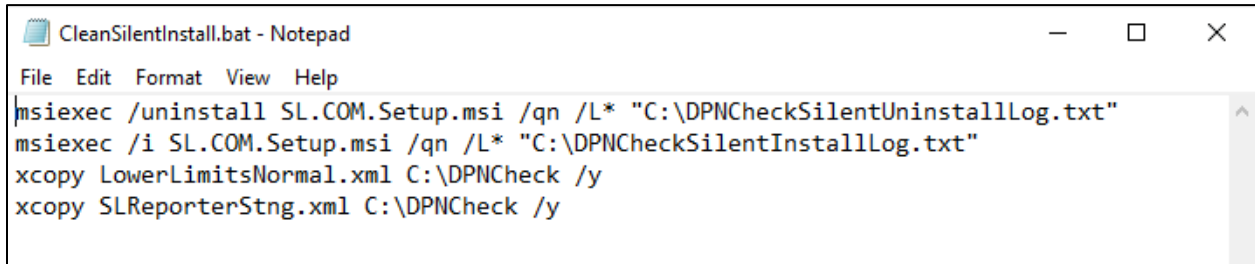
14.2 Remote Install Examples

Batch file examples are provided by DPNCheck as part of the Remote Installation Package downloaded from the DPNCheck Reporter website. These are intended to show what is necessary for your IT organization to create its own remote installation using their preferred 3rd party tools and scripts.

Most of the examples below assume the default datastore path of C:\DPNCheck. For more detail on the Datastore functionality, see Section 8.4: Storing Reporter Studies and Patient Record Outputs, and for more information regarding use of the same Datastore path for networked systems, see Section 15: Appendix E: Using the Same Network Datastore Location
for Multiple Systems. For a full description of the files used by Reporter that may be needed in the remote install (dependent upon your organization's customization of settings), see Section 13.2: Settings Locations.

14.2.1 Uninstall and Install

CleanSilentInstall.bat performs an initial uninstall, then install of Reporter.

```
CleanSilentInstall.bat - Notepad                              —    □    ×
File  Edit  Format  View  Help
msiexec /uninstall SL.COM.Setup.msi /qn /L* "C:\DPNCheckSilentUninstallLog.txt"
msiexec /i SL.COM.Setup.msi /qn /L* "C:\DPNCheckSilentInstallLog.txt"
xcopy LowerLimitsNormal.xml C:\DPNCheck /y
xcopy SLReporterStng.xml C:\DPNCheck /y
```

This batch file performs the following operations:

1. This batch file first uninstalls Reporter (any existing files in C:\DPNCheck remain).
2. A log file is created in location C:\DPNCheck\DPNCheckSilentUninstallLog.txt for logs related to the initial uninstall. This location can be configured.
3. The Reporter application is installed to the local PC.
4. A log file is created in location C:\DPNCheck\DPNCheckSilentInstallLog.txt for logs related to the installation. This location can be configured.
5. The LowerLimitsNormal.xml file (containing the Normal Limits setting) from the Silent Install folder is copied into the C:\DPNCheck folder, overwriting any existing limits file.
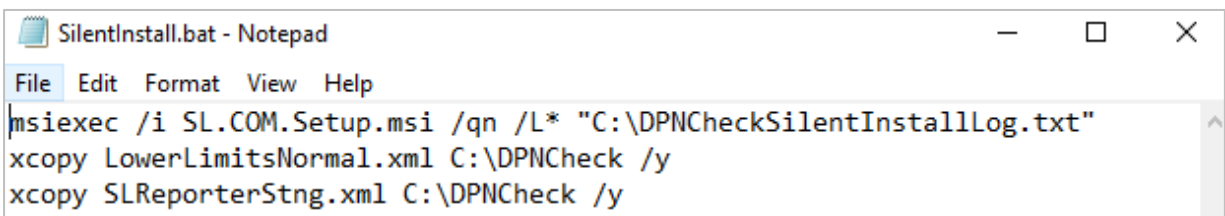6. The SLReporterStng.xml (containing the majority of the settings for Reporter) from the Silent Install folder is copied to the C:\DPNCheck folder, overwriting any existing settings file.

14.2.2 Install Only, settings on Local Drive

SilentInstall.bat performs an installation of Reporter.

```
SilentInstall.bat - Notepad                              —    □    ×
File  Edit  Format  View  Help
msiexec /i SL.COM.Setup.msi /qn /L* "C:\DPNCheckSilentInstallLog.txt"
xcopy LowerLimitsNormal.xml C:\DPNCheck /y
xcopy SLReporterStng.xml C:\DPNCheck /y
```

This batch file performs the following operations:

1. The Reporter application is installed to the local PC.
2. A log file is created in location C:\DPNCheck\DPNCheckSilentInstallLog.txt for logs related to the installation. This location can be configured.
3. The LowerLimitsNormal.xml file (containing the Normal Limits setting) from the Silent Install folder is copied into the C:\DPNCheck folder, overwriting any existing limits file.
4. The SLReporterStng.xml (containing the majority of the settings for Reporter) from the Silent Install folder is copied to the C:\DPNCheck folder, overwriting any existing settings file.

14.2.3 Install Only, Settings on Network drive
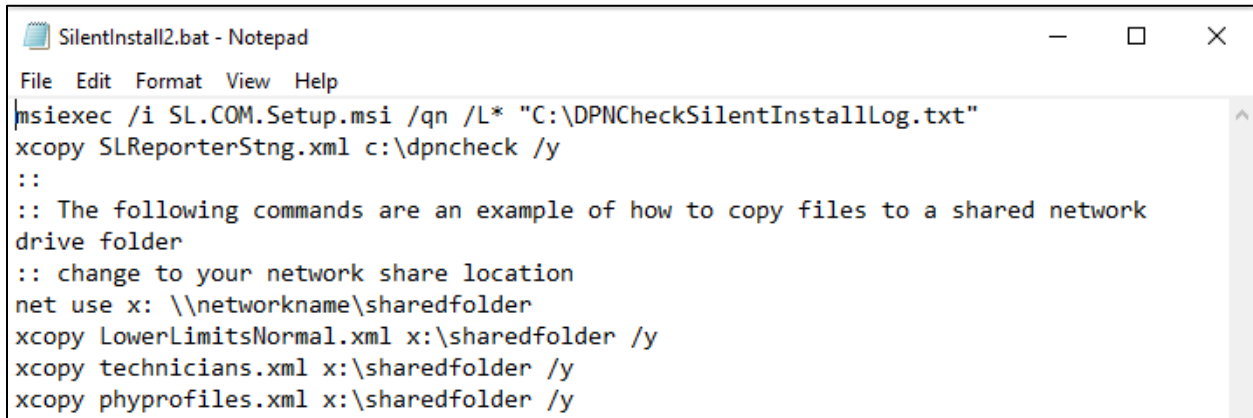
SilentInstall2.bat performs an installation of Reporter and provides examples of commands used to copy files onto a network location.

```
SilentInstall2.bat - Notepad                                    —    □    ×
File  Edit  Format  View  Help
msiexec /i SL.COM.Setup.msi /qn /L* "C:\DPNCheckSilentInstallLog.txt"
xcopy SLReporterStng.xml c:\dpncheck /y
::
:: The following commands are an example of how to copy files to a shared network
drive folder
:: change to your network share location
net use x: \\networkname\sharedfolder
xcopy LowerLimitsNormal.xml x:\sharedfolder /y
xcopy technicians.xml x:\sharedfolder /y
xcopy phyprofiles.xml x:\sharedfolder /y
```
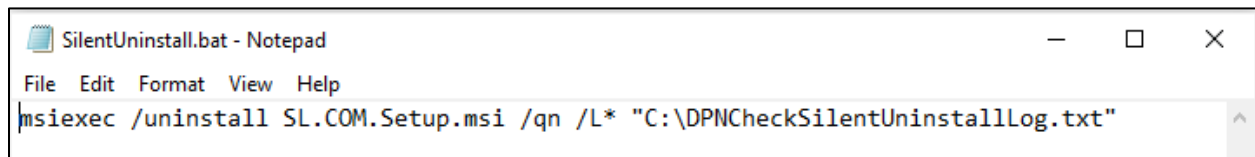
This batch file performs the following operations:

1. The Reporter application is installed to the local PC.
2. A log file is created in location C:\DPNCheck\DPNCheckSilentInstallLog.txt for logs related to the installation. This location can be configured.
3. The LowerLimitsNormal.xml file (containing the Normal Limits setting) from the Silent Install folder is copied into the C:\DPNCheck folder, overwriting any existing limits file.
4. The SLReporterStng.xml (containing most of the settings for Reporter) from the Silent Install folder is copied to the C:\DPNCheck folder, overwriting any existing settings file.

Note: Command examples are provided for copying two settings files, Technicians.xml (containing the technician list) and Physicians.xml (containing the physician list) onto a network location. Note that example Technician and Physician settings files are not included in the Silent Install package; to use this example, you should copy those files from your master copy local install into the Remote Install folder. See Section 13.2: Settings Locations for a full list of settings files that may be needed in the remote install process.

14.2.4 Uninstall Only

SilentUnInstall.bat performs an uninstall of Reporter; all C:\DPNCheck files remain.

```
SilentUninstall.bat - Notepad                                    —    □    ×
File  Edit  Format  View  Help
msiexec /uninstall SL.COM.Setup.msi /qn /L* "C:\DPNCheckSilentUninstallLog.txt"
```

This batch file performs the following operations:

1. This batch file uninstalls Reporter (any existing files in C:\DPNCheck remain).
2. A log file is created in location C:\DPNCheck\DPNCheckSilentUninstallLog.txt for logs related to the initial uninstall. This location can be configured.

14.3 Example Workflow for Configuring Reporter for a Remote Installation

The Remote installation package supports two types of installation:

- New: Installation on a system with no previous instance of Reporter
- Upgrade: Upgrade from Communicator or a previous version of Reporter

For both types of installation, the IT Administrator must create a Master Copy of the Reporter version 2.3 application to generate a Remote Install package containing the appropriate Reporter settings to be used in your organization. Note: It is critical to clarify how the settings should be set for your organization to ensure consistent use of Reporter by end users as some settings affect user data entry and display of the test results.

14.3.1 Workflow for Remote Installation

Step 1: Install a local copy of the Reporter application. This will serve as the Master Copy.

Step 2: After installation is complete, open Reporter and configure the settings as determined by your organization. For a full list of settings and defaults, see Section 13: Appendix C: Reporter Applications Settings Summary. As part of this review, you need to determine whether or not your endpoints will share the same set of settings. If some settings (for example, Technician List or Cloud groups) may differ between endpoints, this must be taken into account when creating your Remote Install package. See Section 14.5: Notes on use of Remote Install with Differing Endpoint settings for more detail.

Step 3: Once settings have been saved, create a Remote Install package and transfer the required settings files to that package. See Section 13.2: Settings Locations for detail on settings file names and locations.

Step 4: Push Remote Install using preferred tools. Batch file examples are provided earlier in this appendix.

14.4 Settings & Process for using Lock settings

A selection of the Reporter settings (see Section 13: Appendix C: Reporter Applications Settings Summary) may be locked from end user editing when installing remotely. When using the lock feature, settings are locked as a group; they may not be locked individually.

To enable the lock, when configuring settings of the master copy of Reporter (See section 7.5.3), first configure all other settings as needed by the organization. The lock setting should be configured last by setting "Lock local user" to "On" in the Security settings. Once this change is made and Reporter closes, the Settings file has now been updated to lock the settings. However, do not restart the Reporter Application. If you restart the master copy application *after* saving this particular setting, it will revert to "Off" and you will need to repeat the process.
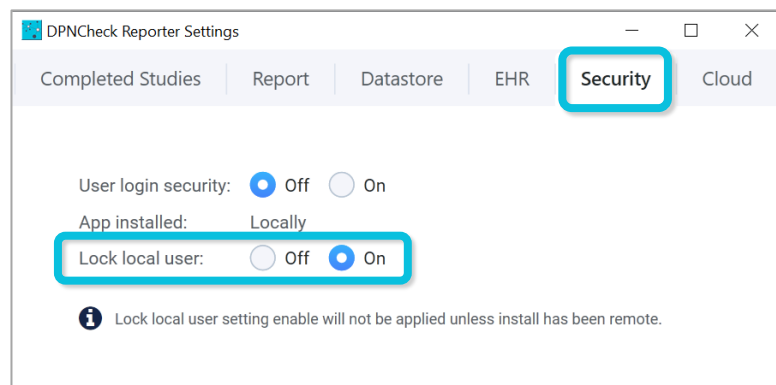
Before including the settings file (SLReporterStng.xml) in your Remote Install files for distribution, check to ensure that the "locklocaluser" key has been properly set to "yes". If not, open the Master Copy of Reporter, navigate to Security settings, set "Lock local user" to "On", save setting and close Reporter.

Once a Remote Install is performed and the settings file contains the lock setting set to "yes", Reporter will detect that the install has been performed remotely and the lock setting will persist for all remotely installed endpoints.

14.5 Notes on use of Remote Install with Differing Endpoint settings

As seen in Section 13.2: Settings Locations, it is possible that your organization may wish to have variation of the settings between different endpoints (e.g., Cloud site name, Technician Lists that differ per site). This must be considered when planning the remote installation. You may need to have multiple variations of the settings files in order to send to different groups of endpoints, such as by site. It is therefore critical to clarify how the settings should be set for your organization, considering grouping by different endpoints, in planning and executing the remote installation.

A full list of settings and locations of setting files are shown in Section 13: Appendix C: Reporter Applications Settings Summary. Full description of how each setting functions within the operation of the Reporter application is outlined in Section 8: Reporter Operation.

15 Appendix E: Using the Same Network Datastore Location for Multiple Systems

For enterprise customers, IT may specify the same Private Folder and Share Folder for multiple endpoints. Because a unique Datastore Directory will be created for each endpoint PC, study files from each PC (files with extension .nmx) will be saved in a Datastore Directory unique to this PC, under the same Private Folder; this avoids commingling of DPNCheck study data. PDF reports and HL7 exports may be saved in a centralized location under Share Folder as described above.

As stated above, the files for Normal Limits, Physician Profiles, Technician Profiles, and Interpretation Notes are stored in the Private Folder, <u>outside</u> of the uniquely named Datastore Directories. This means that if multiple PCs are set to the same Private Folder, these files will be accessible to all of those endpoint PCs. This may be advantageous for situations where the PCs are part of a site or group of sites that share a common set of physicians, technicians, normal limits, and interpretation notes.

Below are examples of the structure of saving data when multiple endpoint PCs utilize various options for Private Folder and Share Folder.

Set up for PC 1 (named PCName1) and PC2 (named PCName2)	Reporter Application Behavior
Case 1: Saving Locally <u>Private Folder</u>: set to C:\DPNCheck (default) <u>Share Folder</u>: not specified	Each Reporter saves its data under C:\DPNCheck directory on its own local drive. Each Reporter can have its own Physician Profile, Technician Profile, Interpretation Notes, and Normal Limit settings.
Case 2: Saving to Network, *use of Private Folder only* <u>Private Folder</u>: set to \\network\folderA <u>Share Folder</u>: not specified	Reporter on PC 1 will save its data under \\network\folderA\PCName1.datastore folder. Reporter on PC 2 will save its data under \\network\folderA\PCName2.datastore folder. Both Reporters will share the same Physician Profile, Technician Profile, Interpretation Notes, and Normal Limit settings.
Case 3: Saving to Network, *use of both Private and Share Folders* <u>Private Folder</u>: set to \\network\folderA <u>Share Folder</u>: set to \\network\folderB Share options enabled	Reporter on PC 1 will save its data under folder \\network\folderA\PCName1.datastore Reporter on PC 1 will save its PDF reports and export files under folder \\network\folderB (same as PC 2) Reporter on PC 2 will save its data under folder \\network\folderA\PCName2.datastore Reporter on PC 2 will save its PDF reports and export files under folder \\network\folderB (same as PC 1) Both Reporters will share the same Physician Profile, Technician Profile, Interpretation Notes, and Normal Limit settings.

Set up for PC 1 (named PCName1) and PC2 (named PCName2)	Reporter Application Behavior
Case 4: Saving to Network, use of both Private and Share Folders but Private Folders are unique <u>Private Folder PC1</u>: set to \\network\folderA\Site1 <u>Private Folder PC2</u>: set to \\network\folderA\Site2 <u>Share Folder</u>: set to \\network\folderB Share options enabled	Reporter on PC 1 will save its data under folder <u>\\network\folderA\Site1\PCName1.datastore</u> Reporter on PC 1 will save its PDF reports and export files under folder <u>\\network\folderB</u> (same as PC 2) Reporter on PC 2 will save its data under folder <u>\\network\folderA\Site2\PCName2.datastore</u> Reporter on PC 2 will save its PDF reports and export files under folder <u>\\network\folderB</u> (same as PC 1) Each Reporter can have its own Physician Profile, Technician Profile, Interpretation Notes, and Normal Limit settings.

IT Note: The Reporter Software automatically sets up the required subfolder directory hierarchy for both the Private Folder and the Share folder. Therefore, it is critical that the Datastore folders <u>remain constant</u> and network accessible once clinicians/users begin processing patient tests and data is saved to the Private and Share Folders.

IT Note: During IT planning, the network share location should be set up prior to setting the folder in Datastore Settings; this ensures that the proper access and permissions have been configured. Note that if a location is specified in Datastore Settings (for either Private Folder or Share Folder) that does not yet exist, the Reporter Application will be unable to start. Note the Private and Share Folders must be different; they <u>cannot</u> be mapped to the same folder.

IT Note: Folder Permissions
The user(s) of DPNCheck Reporter will need read/write permissions for the Private Folder and Share Folder specified via the Datastore Settings for the endpoint PC that the user(s) will be accessing to use Reporter. These permissions must be set prior to the user using the Reporter Application.

16 Appendix F: De-identified Data Stored in Cloud

When the Upload to Cloud setting is enabled, Reporter sends de-identified data to the DPNCheck Cloud. The data below are included for each completed study.

Device Record	
Device Serial Number	The Serial Number of the DPNCheck device used for the test.
Total Test Count	The total test count, total valid test count, and total error test count as recorded by the DPNCheck device used for the test.

Site Record	
Technician Name	Name of Technician if entered on Report tab
Physician Name	Name of Physician if entered on Report tab
Physician NPI	National Provider Number if entered on Report tab
Site Name	Site Name designated (optional) in Cloud Settings
Local Computer Name	Windows PC Name for computer from which the study was uploaded to the cloud
Domain Name	Windows domain name for the computer from which the study was uploaded to the cloud
Username	Windows username for the computer from which the study was uploaded to the cloud
Parent Name	Parent Name designated (optional) in Cloud Settings
Grandparent Name	Grandparent Name designated (optional) in Cloud Settings
Customer Identifier	Customer Identifier designated in Cloud Settings; assigned by DPNCheck

Patient Record	
Gender	Gender selected for the study within Patient tab
Age	Age calculated for the study in Patient tab; limit of 90 years. applied for de-identification purposes
Height	Height entered in Patient tab (dependent on requirement of height entry based on Normal Limit setting); limit of 78 inches (198 cm for male/unspecified gender) and 72 inches (183 cm) for female applied for de-identification purposes
Weight	Note: as weight entry is not supported in Reporter version 2.3, this only applies to studies that are created on an earlier version of the application but uploaded to cloud after upgrade.

Results Record	
Test Date	Date and time of first left or right test in a study when uploaded from DPNCheck devices
Temperature	Temperature measured by the DPNCheck device, in degrees C
Undetectable Flag	Indicates whether result was undetectable
Amplitude	Amplitude in microvolts
Conduction Velocity	Conduction Velocity in meters/second
Normal Limits	Type of normal limits used
Amplitude Normal Limit	Limit under which result is considered abnormal, amplitude
Conduction Velocity Normal Limit	Limit under which result is considered abnormal, conduction velocity

Interpretation Record	
Interpretation Selection	Manual interpretation category (no peripheral neuropathy, mild peripheral neuropathy, moderate peripheral neuropathy, severe peripheral neuropathy, other)

17 Appendix G: Notes on Age Calculation

Reporter uses two different reference dates in order to calculate Age based on the entered Birth Date.

For the age displayed on the Patient Tab, the reference date is the current date.

For the age used in the Normal Limits calculation, Cloud records, and Study Search, the reference date is the date of the Study, i.e., date when test was uploaded from the device.