**DPNCheck®**

Cloud Use Guide

DPNCheck Cloud Overview

The DPNCheck Cloud ("Cloud") is a cloud database that aggregates de-identified DPNCheck data that has been uploaded to the DPNCheck Reporter ("Reporter") 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.
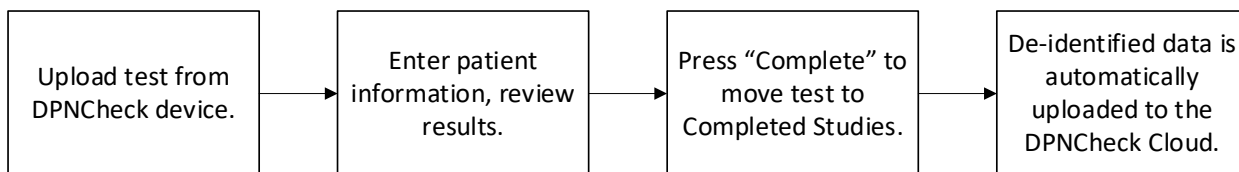
Cloud Structure and Flow of Data

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 and reviewing results, and then clicking Complete (button on Reporter screen).
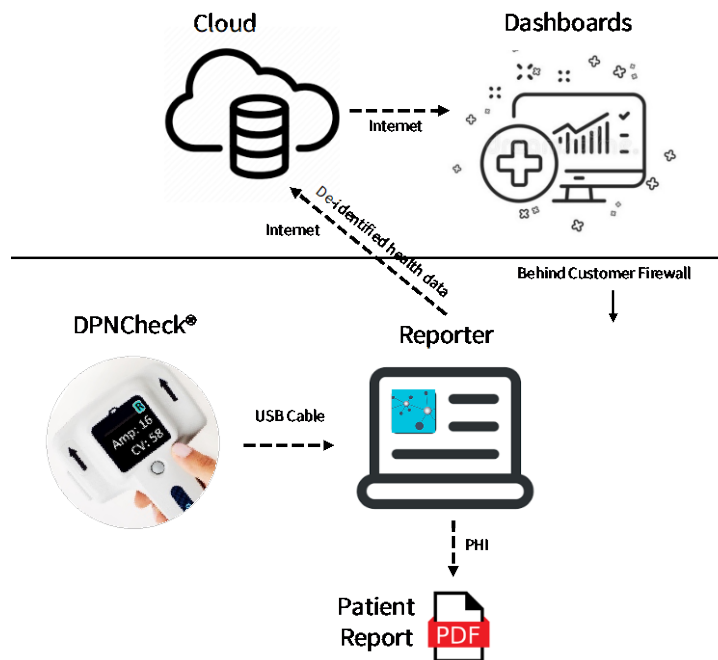
If the Reporter application is configured for Cloud upload, then a de-identified subset of the study data is queued for transmission to the Cloud. Queued data is sent to the database whenever the endpoint has an active internet link. New data is synchronized to the Cloud at 1-minute intervals.

User flow for Cloud upload (Cloud settings configured and active internet connection):

Upload test from DPNCheck device.	Enter patient information, review results.	Press "Complete" to move test to Completed Studies.	De-identified data is automatically uploaded to the DPNCheck Cloud.

See section below, De-identified Data Stored in Cloud for further detail on the de-identified data sent to the Cloud. See section below, Cloud Privacy and Data Security 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.

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, and the IDs may be used to control data access.

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:
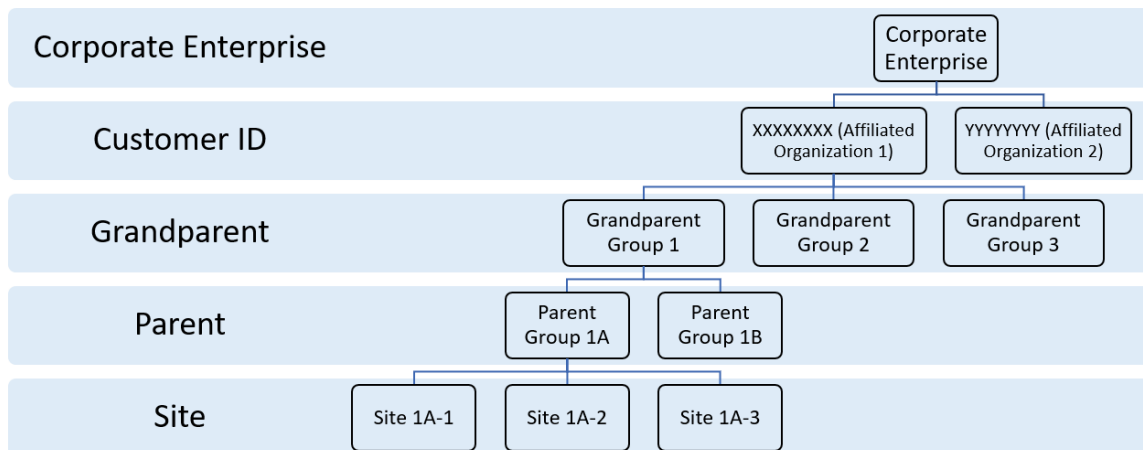
Dashboard Overview

The data in the Cloud is available via web-based dashboards using Tableau®. 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.
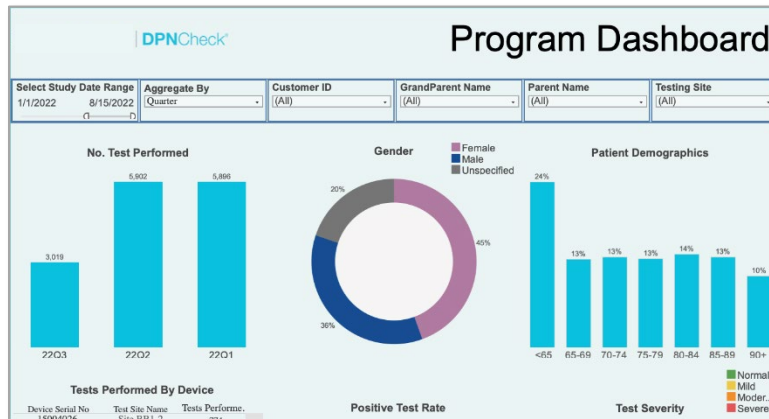
Note: Raw (de-identified) data may be downloaded from the Tableau® Dashboard if desired.

Dashboard Access

DPNCheck will provide login credentials to the customer as requested. The Customer ID numbers are used to control access, where a Dashboard view comprises one or more Customer IDs. An example is presented below for a customer who has requested two Customer IDs:

Requested Credentials	Access
Login 1	Access to Data for Customer ID1
Login 2	Access to Data for Customer ID2
Login 3	Access to Data for Customer ID1 and ID2

Note that each PC with Reporter installed will be associated with a single Customer ID; multiple PCs may use the same Customer ID.

Cloud Privacy and Data Security

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 the section below, 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.) 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 (www.dpncheck.com/reporter2-3eula).

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)

Cloud Customer Use Setup Questionnaire

Access to Cloud Dashboard and underlining cloud data is controlled by login credentials. A unique login credential (email and password) will be associated with one or more Customer IDs. Because Cloud Dashboards present aggregated information for an organization, it is recommended that Customer ID be allocated at the highest organizational level where data aggregation is most useful and access will not compromise data confidentiality.

The Dashboard Viewer (the person who possesses the login credentials associated with one or more Customer IDs) will have access to data from all Reporter instances with the same Customer ID through Cloud Dashboard and underling cloud data. However, the Dashboard Viewer has the ability to view a subset of the data by utilizing built-in filtering options. For example, the Dashboard Viewer can select data from one or more Sites under a selected Parent organization as long as the selected Parent organization falls under the business unit to which the Customer IDs are assigned (see The Hierarchical Relationship Diagram on Page 2).

Please complete the following Setup questionnaire:

Customer Organization Name:	
Primary Point of Contact Assigned Customer ID and Cloud Dashboard credentials will be sent to this email.	**Name**:
	Email:
	Phone Number:
For each Customer ID, please complete the following (add or remove lines if needed):	
Customer ID 1	(Assigned by DPNCheck)
Business Unit Name 1 Name to be associated with above ID	
Customer ID 2	(Assigned by DPNCheck)
Business Unit Name 2 Name to be associated with above ID	
Customer ID 3	(Assigned by DPNCheck)
Business Unit Name 3 Name to be associated with above ID	