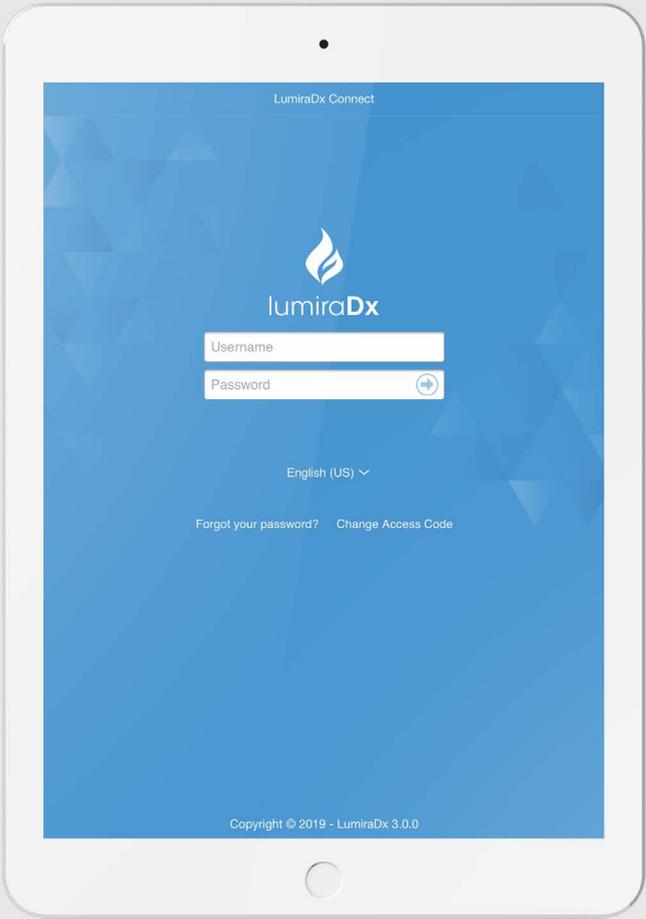


 LumiraDx™ Connect User Manual



Connect User Manual

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1 Abbreviations

EHR	Electronic Health Record
FIPS	Federal Information Processing Standard
GDPR	General Data Protection Regulation
ID	Identification
SSID	Service Set Identifier
LIS	Laboratory Information System
HIS	Hospital Information System

2 Overview of LumiraDx Connect

LumiraDx Connect is a smart integrated connectivity platform which allows users to configure and manage LumiraDx point of care Platform Instruments remotely, and transfer test results into an existing patient's Electronic Health Record (EHR). This is powered by LumiraDx Connect Manager and EHR Connect.

To use LumiraDx Connect it is advised the following checks are completed and information acquired from your IT department prior to continuing to setup and configure LumiraDx Connect:

- Local network configuration
 - Check whether there is a preference for Ethernet or Wireless connection
 - If your IT network uses a "Proxy" you will require the following information:
 - "Hostname" of the Proxy
 - "Port" number of the Proxy
 - Username and password, if necessary.
 - If you will use Wi-Fi for connectivity, you will need to obtain the following information:
 - The 'SSID' name of the Wi-Fi
 - The password for your Wi-Fi
 - If your local IT network requires access to be granted to secure websites, you will need to allow outbound access to *.lumiradx.com on ports 80 & 443.
- Installing software on mobile devices
 - You will need to be able to install an app from the public app stores on a mobile / tablet device.

Standalone

Run patient tests and quality control tests.

Store test results together with time, date and patient ID.



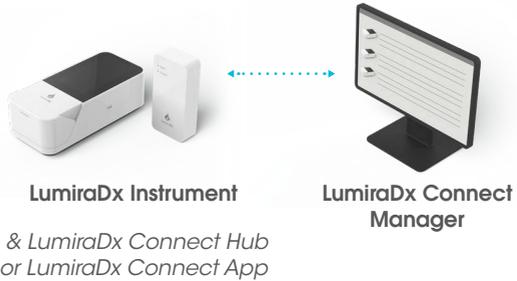
LumiraDx Instrument

Managed

Configure single or multiple Instruments.

Create WorkGroups and user login credentials.

Manage compliance and governance functions.



EHR Connected

Integrate with Electronic Health Record for transfer of patient test results.

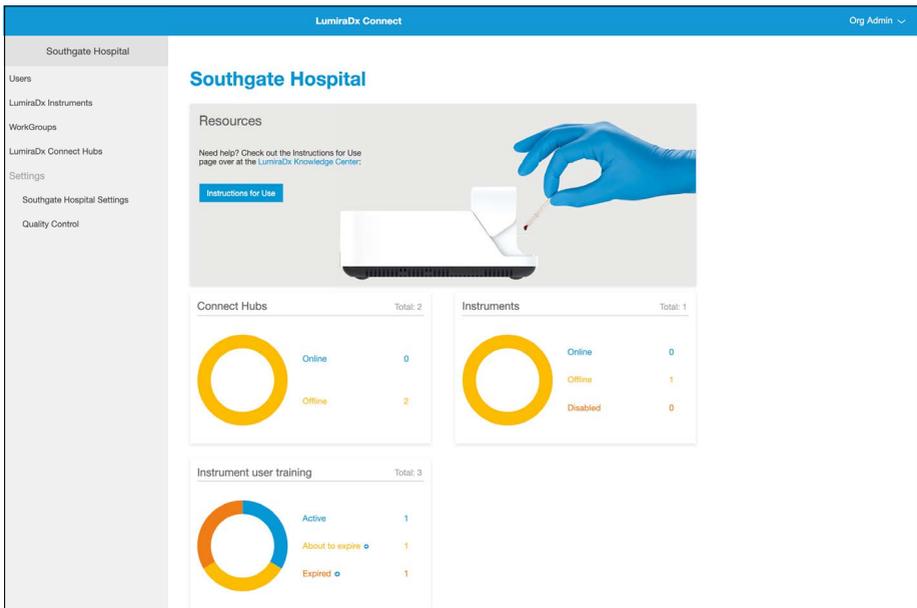
View patient test results in your LIS or HIS.



2.1 LumiraDx Connect Manager

LumiraDx Connect Manager provides an Administrator with the opportunity to oversee remote patient and quality control tests, making quality management easier. LumiraDx Connect Manager is a cloud-based website application and mobile application for native iOS and Android used for fast, accurate management of all your LumiraDx Instruments. It can be used to:

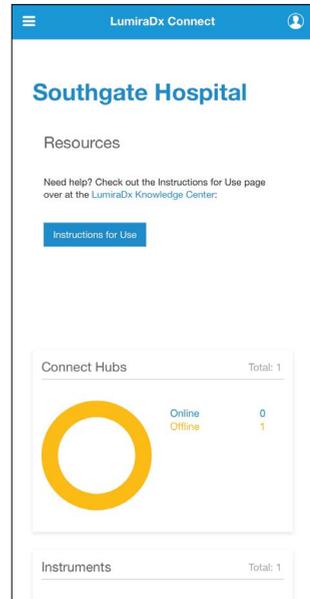
- Set up WorkGroups
- Assign users and LumiraDx Instruments to WorkGroups for ease of management
- Manage users and administrators
- Monitor and manage Instruments and Connect Hub (s)
- View Instrument test and Quality Control results
- Manage Quality Control Policy
- Manage Users training status



2.2. LumiraDx Connect App

LumiraDx Connect App is an application for native iOS and Android which acts as a mobile version of LumiraDx Connect Manager. In addition to allowing access to Connect Manager from a mobile or tablet, the LumiraDx Connect App can also be used to:

- Perform initial configuration and connection of Connect Hubs to a Wi-Fi network
- Act as an alternative method of connecting an Instrument to LumiraDx Connect when operating out of range of a Connect Hub



2.3 LumiraDx Connect Hub

LumiraDx Connect Hub is a standalone module which allows Instruments to automatically communicate with the Connect Manager application through a Bluetooth Low Energy connection.



The Connect Hub:

- Seamlessly and wirelessly transfers test results collected by LumiraDx Instruments
- Is highly secure – Instruments only communicate through designated hubs
- Automatically connects to Instruments within a 10-meter range
- Connects to a network using Wi-Fi or Ethernet
- Offers support for up to 7 Instruments from each Connect Hub simultaneously
- Has a simple interface showing power and connection status
- Is provided with interchangeable power blades which are compatible with power outlets in most geographic areas
- Is easy to set up using the LumiraDx Connect App

2.4 EHR Connect

EHR Connect is an additional service that enables seamless connection between the LumiraDx Instrument and existing Electronic Health Record systems allowing test results to be saved to patient medical records. Integration with a wide range of healthcare systems is supported and the technology is compatible with industry operation standards such as HL7, GDT and others, and is flexible to support both cloud and local based installations.

EHR Connect can provide additional support for the transfer of test results, patient positive confirmation at the time of the patient test, administration of Instrument Operators and Quality Control policy settings either through seamless integration with Connect Manager or an Organization's existing middleware system. The extent of the integration depends on the level of management supported by the middleware provider.

Further information about this additional service can be obtained from LumiraDx Customer Services.

3 Getting started

3.1 Unpacking the Connect Hub

The LumiraDx Connect Hub package includes the following contents:

- LumiraDx Connect Hub
- LumiraDx Connect Hub power blades
- LumiraDx Connect Hub pack insert

Inspect the Connect Hub and packaging for damage before use. For safety reasons, do not plug in a damaged Connect Hub, and report any damage to Customer Services. Refer to the Customer Services chapter of this Connect User Manual for contact information.

3.2 Installing the LumiraDx Connect App

Your organization’s designated administrator will oversee the LumiraDx setup and will receive initial connectivity details from LumiraDx. These details will be needed for the first-time login to Connect Manager.

The LumiraDx Connect App is available through Android and iOS app stores. To install the Connect App on to a mobile device, open the app store, search for LumiraDx Connect and install the app.

Note: On Android devices, if the app asks, “Allow Connect to access this device’s location?” Select “Allow”. Android devices will not allow Bluetooth to connect unless access to the device’s location is allowed.

1. Open the app and enter the Access Code provided.
2. Tap/select ‘Validate Access Code’.
3. Enter username, then password.
4. Tap ‘Login’.



3.3 Powering the Connect Hub

Using the correct Connect Hub power blade, plug the Connect Hub into a wall socket. When the Connect Hub is powered, the 'Power' indicator will light up.

3.4 Connect Hub Configuration

Once configured, Connect Hubs will begin transferring data automatically between LumiraDx Instruments, Connect Manager and Electronic Health Record. Connect Hubs can only be configured using the LumiraDx Connect App running on a mobile device. The mobile device must be within 10 meters of the Connect Hub for successful setup.

3.5 Configuring a Connect Hub with a wired Ethernet connection

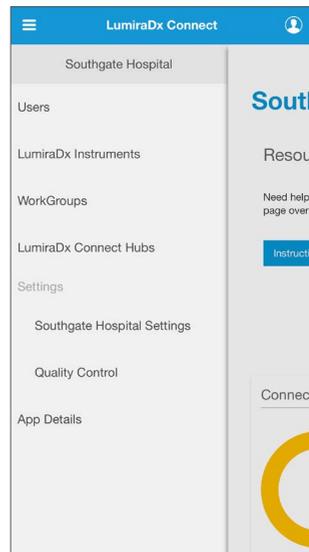
If your organization does not require use of a proxy, you may be able to start using your Connect Hub by simply connecting it to the power supply and inserting an Ethernet cable into the Connect Hub Ethernet port.

If your organization does require use of a proxy, please follow the following steps:

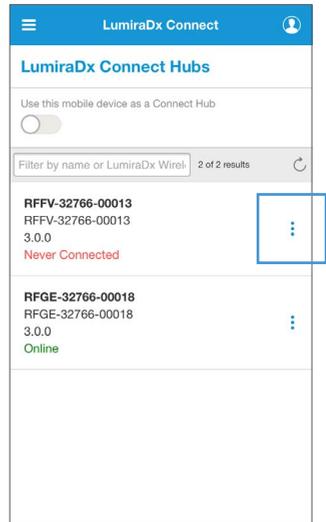
1. Login to Connect App on a mobile device and tap the menu icon  at the top left of the screen to access the menu

Note: Make sure Bluetooth is turned on for your mobile device

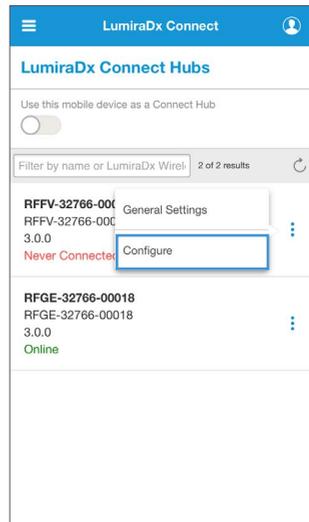
2. Tap 'LumiraDx Connect Hubs'.



3. Tap the Action Menu \vdots for the Connect Hub you wish to configure.

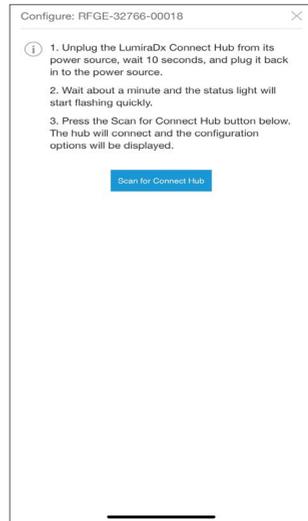


4. Tap 'Configure' from the drop-down menu.



5. Unplug the LumiraDx Connect Hub from its power source, wait 10 seconds, and plug it back into the power source.
6. Insert one end of the Ethernet cable into the Connect Hub Ethernet port and the other end of the cable to either the wall socket Ethernet port or a router.
7. Wait about a minute and the Connect status light will start flashing quickly.
8. Tap 'Scan for Connect Hub'

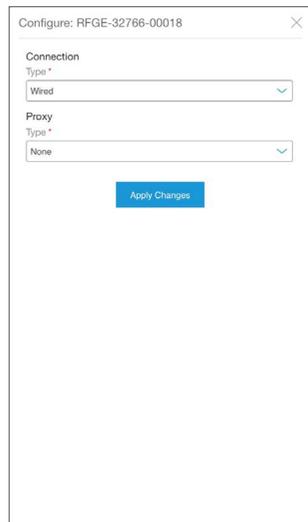
The Connect App will now connect to the Connect Hub and you will now see the configuration settings for the Connect Hub.



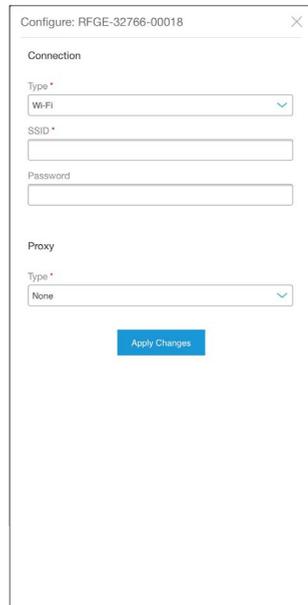
9. In 'Connection' section, select 'Wired'.
10. You may need to contact your IT department for your 'Proxy' details. If your organization does not require use of a proxy, select 'None' in the 'Proxy' menu.

If your organization requires use of a proxy, select 'Manual' in the 'Proxy' menu then complete the fields below.

Note: if you do not know what values to enter in these fields, ask your Network Administrator.



11. Tap 'Apply Change'.



Configure: RFGE-32766-00018

Connection

Type *
Wi-Fi

SSID *
[Empty field]

Password
[Empty field]

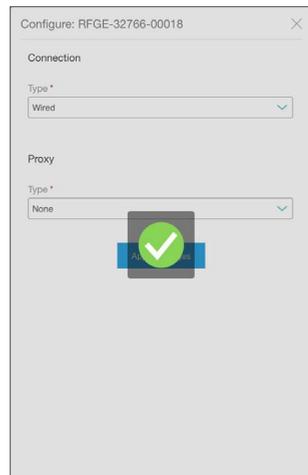
Proxy

Type *
None

Apply Changes

12. A confirmation message will show that the configuration settings have been applied.

13. The Connect Hub "Connect" light will change from a flashing green light to a solid green light within 60 seconds.



Configure: RFGE-32766-00018

Connection

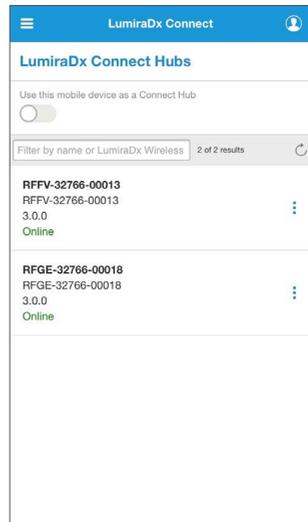
Type *
Wired

Proxy

Type *
None

[Green Checkmark Icon]

14. The Connect App will now show that the Connect Hub is online.

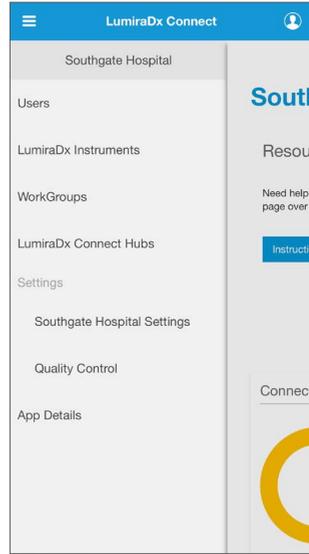


3.6 Configuring a Connect Hub with a wireless connection

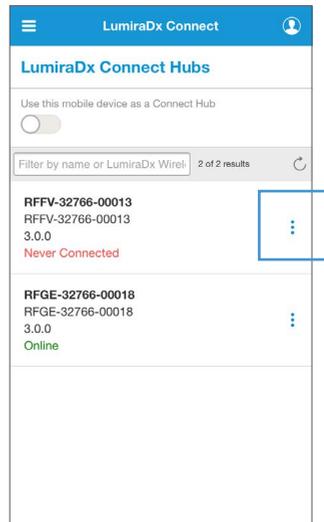
1. Login to Connect App on a mobile device and tap the menu button  at the top left of the screen to access the menu.

Note: Make sure Bluetooth is turned on for your mobile device.

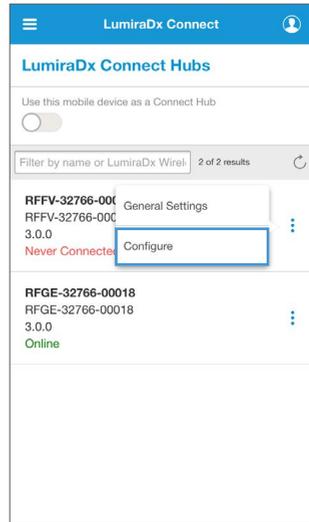
2. Tap 'LumiraDx Connect Hubs'.



3. Tap the Action Menu  for the Connect Hub that you wish to configure.

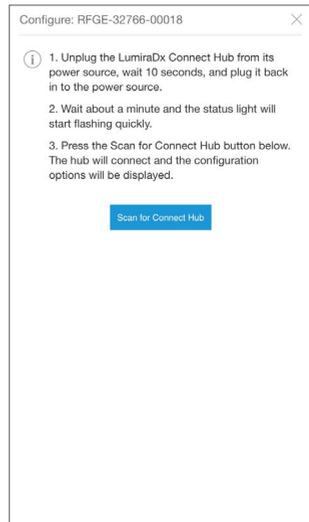


4. Tap 'Configure' from the drop-down menu.



5. Unplug the LumiraDx Connect Hub from its power source, wait 10 seconds, and plug it back into the power source.
6. Wait about a minute and the Connect status light will start flashing quickly.
7. Tap 'Scan for Connect Hub'

The Connect App will now connect to the Connect Hub and you will now see the configuration settings for the Connect Hub



8. In 'Connection' section, select 'Wi-Fi'.
9. In 'SSID', enter the Service Set Identifier (SSID or network name) for the Wi-Fi network.
Note: if you do not know what the SSID is, ask your Network Administrator.
10. Enter the Wi-Fi 'Password'.
11. If your organization does not require use of a proxy, select 'None' in the 'Proxy' menu.

If your organization requires use of a proxy, select 'Manual' in the 'Proxy' menu then complete the fields below.

Note: if you do not know what values to enter in these fields, ask your Network Administrator

Configure: RFGE-32766-00018

Connection

Type *
Wi-Fi

SSID *
[Empty]

Password
[Empty]

Proxy

Type *
None

Apply Changes

12. Tap 'Apply changes'.

Configure: RFGE-32766-00018

Connection

Type *
Wi-Fi

SSID *
[Empty]

Password
[Empty]

Proxy

Type *
Manual

Hostname *
URL or IP Address
[Empty]

Port *
0

Username
[Empty]

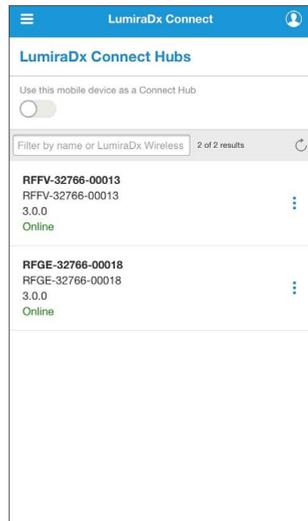
Password
[Empty]

Apply Changes

13. A confirmation message will show that the configuration settings have been applied.
14. The Connect Hub “Connect” light will change from a flashing green light to a solid green light within 60 seconds.



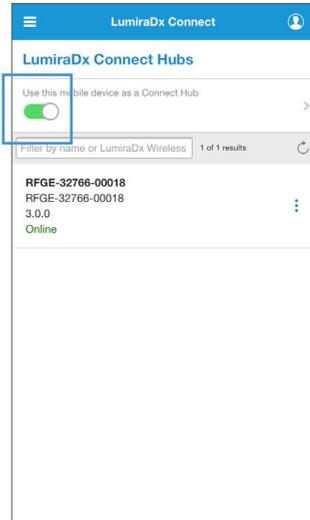
15. The Connect App will now show that the Connect Hub is online.



3.7 Using a mobile device as a Connect Hub

If a LumiraDx Instrument is out of range of a Connect Hub but needs to be managed by Connect Manager or to send test results to Connect Manager, a mobile device can be used as an alternative to the LumiraDx Connect Hub.

1. Login to Connect App on a mobile device and tap the menu button  at the top left of the screen to access the menu.
2. Tap 'LumiraDx Connect Hubs'.
3. On the Connect Hubs page, enable the mobile device to act as a Connect Hub by using the slider.
4. Tap the  icon to see what Instruments the mobile device is connected to.



4. Connect Manager system

The Connect Manager website or Connect App can be used to create the administrative infrastructure of the LumiraDx Platform.

Users of Connect Manager and Instruments can have different types of roles:

- **Organization Admin** is an administrator for the entire organization. They can login to Connect Manager, create new users, edit existing users, create WorkGroups and edit the settings of every WorkGroup.
- **WorkGroup Admin** is an administrator for one or more selected WorkGroups. They can login to Connect Manager and add Instrument operators to their specific work groups.
- **Instrument Admin** can login to LumiraDx Instruments, perform setup and upgrades and perform tests.
- **Instrument Operators** can login to LumiraDx Instruments to perform tests.

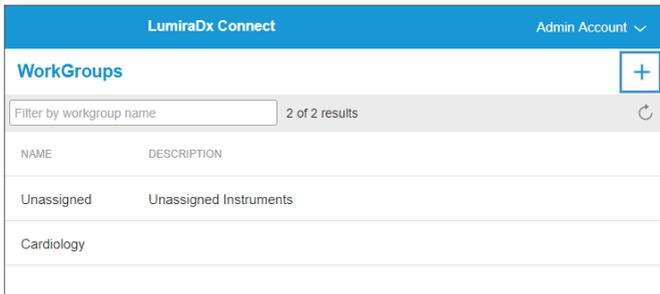
4.1 WorkGroups

Instruments and Users can be assigned to Workgroups (e.g. Cardiology). This allows control of which Users can use which Instruments. The WorkGroup settings area will be not be available and hidden if Instrument Operators are being managed through a middleware provider.

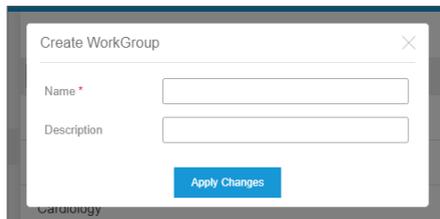
Note: Instruments may only appear in one WorkGroup while Users can be assigned to one or more.

To add a new WorkGroup:

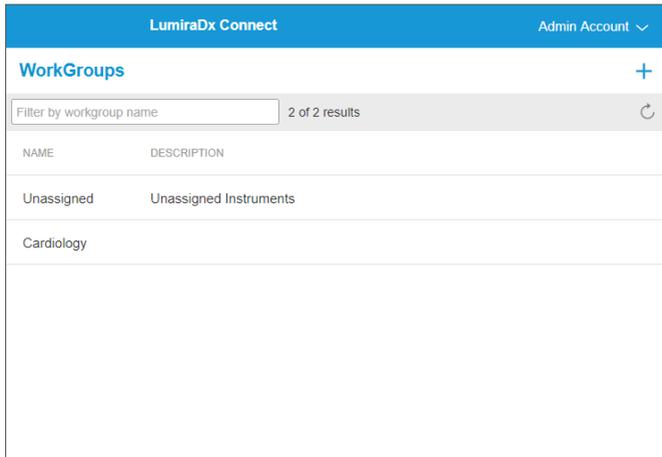
1. Organization Admin must login to Connect Manager.
2. Tap 'WorkGroups' to display the list of existing WorkGroups.
3. Tap +



4. Enter the name of the new WorkGroup
5. Optionally, enter a brief description of the new WorkGroup. This description appears next to the WorkGroup name when selected.



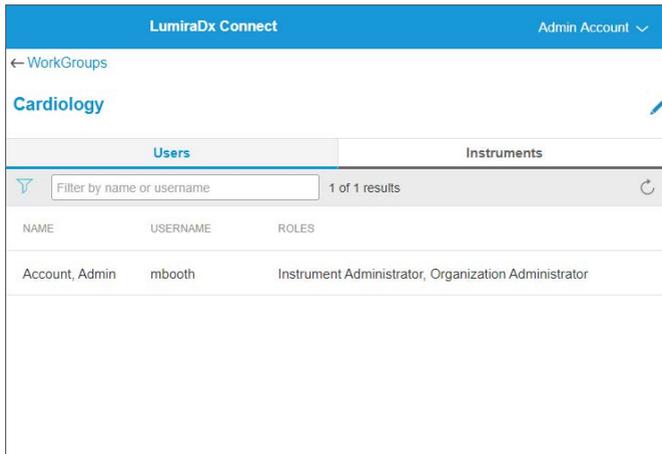
To view the Instruments and Users who belong to a WorkGroup, select the WorkGroup from the list.



The screenshot shows the 'LumiraDx Connect' interface. At the top right, it says 'Admin Account' with a dropdown arrow. Below the header is a section titled 'WorkGroups' with a plus sign icon. There is a search bar labeled 'Filter by workgroup name' and a refresh icon. Below the search bar, it says '2 of 2 results'. A table lists two workgroups: 'Unassigned' with description 'Unassigned Instruments' and 'Cardiology'.

NAME	DESCRIPTION
Unassigned	Unassigned Instruments
Cardiology	

Select 'Users' or 'Instruments' tabs to view the list of Users and Instruments in the WorkGroup.



The screenshot shows the 'LumiraDx Connect' interface. At the top right, it says 'Admin Account' with a dropdown arrow. Below the header is a section titled 'Cardiology' with a pencil icon. There are two tabs: 'Users' (selected) and 'Instruments'. Below the tabs is a search bar labeled 'Filter by name or username' and a refresh icon. Below the search bar, it says '1 of 1 results'. A table lists one user: 'Account, Admin' with username 'mbooth' and roles 'Instrument Administrator, Organization Administrator'.

NAME	USERNAME	ROLES
Account, Admin	mbooth	Instrument Administrator, Organization Administrator

4.2 Users

To edit or create a new User:

Organization Admin must login to Connect Manager

From the Users page, select any User from the list to edit or tap + to create a new User.

Users			+	
Filter by name or username			6 of 6 results	⌵ ⌲
NAME	USERNAME	ROLES		
Active				
Last Name, First Name	admin	Instrument Administrator, Organization Administrator	⋮	
Admin, Org	root.94efa	Organization Administrator	⋮	
Smith, Steven	stevensmith	Instrument Operator, Organization Administrator	⋮	
Training Expiring Soon				
Doe, Jane	jd	Instrument Operator	⋮	
Training Expired				
Doe, John	jdoe	Instrument Administrator, Organization Administrator	⋮	
Disabled				
Doe, Jeff	jeffd	Instrument Operator, Organization Administrator	⋮	

Tap the filter icon to filter the list of users in view.

The screenshot shows the 'Users' page with a filter menu open. At the top, there is a search bar 'Filter by name or username' with '11 of 11' results. Below it is a 'Filters' section with a 'Clear Filters' link. The filters are organized into three categories: Roles, Status, and Sort. Under Roles, there are four options: Instrument Operator, Instrument Administrator, WorkGroup Administrator, and Organization Administrator, each with a green toggle switch. Under Status, there are four options: Active, Training Expired, Training Expiring Soon, and Disabled, each with a green toggle switch. Under Sort, there is a dropdown menu set to 'Username (default)' and two radio buttons: 'Ascending' (selected) and 'Descending'.

Highlighted fields must be completed.

'Username' will be used for logging in to an Instrument or Connect Manager.

An email address can only be used once by a single user within an organisation.

Connect Manager Roles – select one of the following:

- None
- Organization Administrator
- WorkGroup Administrator

The screenshot shows a 'Edit User' dialog box with the following fields and values:

- Username: jd
- Email: instrument@operator.com
- Title: (empty)
- First Name: Jane
- Last Name: Doe
- Initials: (empty)
- Language: English
- Connect Manager Roles: Select from list...
- Instrument Roles: Instrument Operator
- Instrument Workgroups: Emergency Room
- Enforce instrument user training expiry:
- Training valid until: Nov 13 2020

An 'Apply Changes' button is located at the bottom right of the form.

Note: If you select WorkGroup Administrator, you must select the WorkGroups to which the administrator belongs.

Instrument Roles – indicate whether the user is an Instrument Operator.

Select whether enforced training compliance is required and the training expiration date.

Note: If 'Instrument Operator' is selected, the user will be able to login to Instruments and administer tests. Choose the appropriate WorkGroups for this User from the check list that appears.

Users cannot change their WorkGroup or Instrument roles themselves. Changes must be made by another Organization Administrator.

Note: If Instrument Operators are being managed through a middleware provider, the WorkGroup and Instrument Roles will not be available. Instrument Operators will need to be set up through the middleware connected system. Connect Manager Users can still be created and managed through Connect Manager.

Once a new User has been created, an automatic email will be sent to the User's email address containing their initial password which will expire within 24 hours.

To disable or enable a User or to reset a User's password tap the action menu  for that User.

Training Expiring Soon			Reset Password
Doe, Jane	jd	Instrument Operator	
Training Expired			Disable User

Selecting 'Reset Password' will result in an automated email being sent to the User with their new password.

 **Admin User**

Are you sure you want to reset this user's password? A new password will be emailed to the email address on the account.

[Reset Password](#) [Cancel](#)

Instrument Operator Training

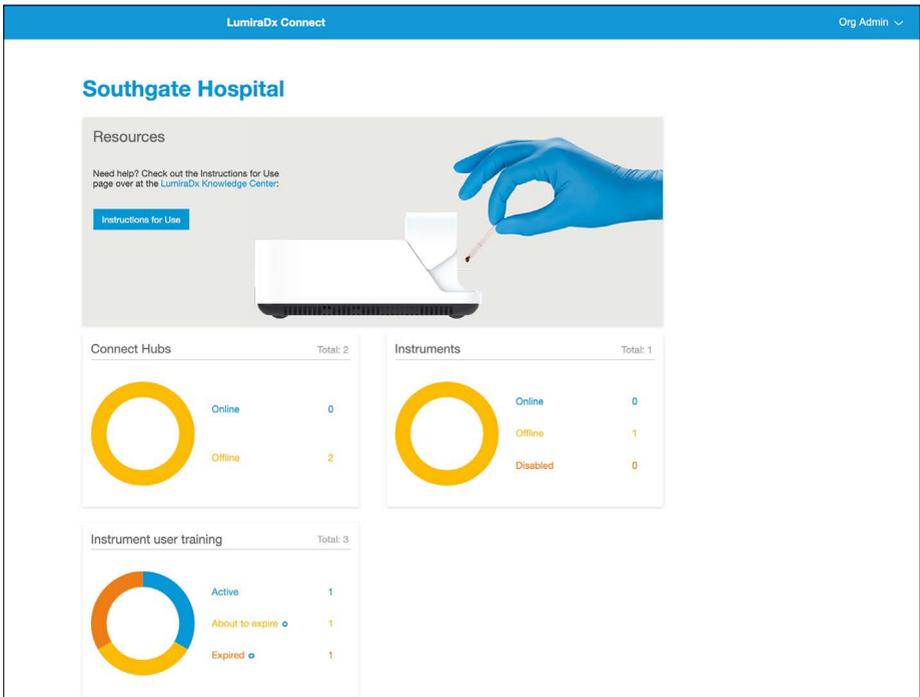
The Instrument Operator Training status can be viewed from the home screen.

Active – Users who are within their training expiration date

About to expire – Users who are within 14 days of training expiration

Expired – Users who have passed their training expiration date. These users are unable to perform patient tests until their training has been updated and a new training expiration date set.

Click on a user status to see a filtered view of those users.

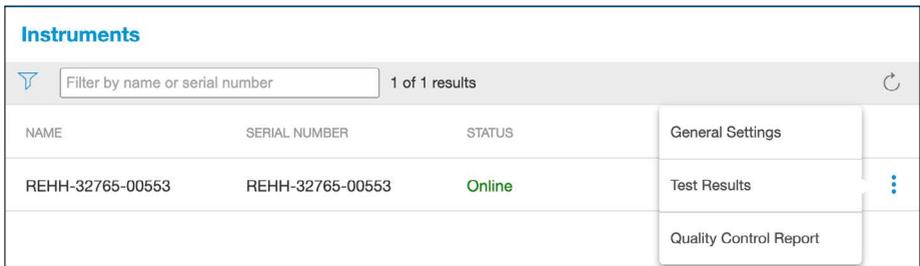


4.3 Instruments

An organization's Instruments can be designated to particular WorkGroups. This is useful if an organization prefers to restrict the use of any Instruments to certain departments. An Instrument's WorkGroup and other settings can be updated via the Instruments page in Connect Manager.

To update an Instrument's general settings:

1. Organization or WorkGroup Admin must login to Connect Manager.
2. Tap 'LumiraDx Instruments'.
3. Tap the action menu button  and 'General Settings' to view and edit the Instrument settings.

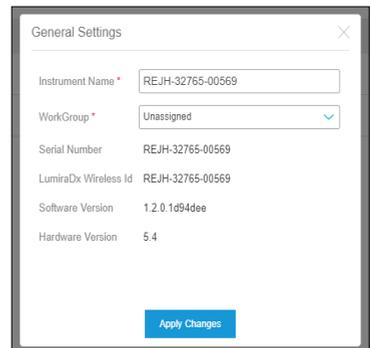


NAME	SERIAL NUMBER	STATUS	
REHH-32765-00553	REHH-32765-00553	Online	<ul style="list-style-type: none">General SettingsTest ResultsQuality Control Report

4. 'Instrument name' – enter a name other than the default for the Instrument.
5. 'WorkGroup' – select the WorkGroup to which the Instrument is assigned.

Note: Instruments are assigned to the "Unassigned" WorkGroup by default. Move the Instruments to a WorkGroup created by (or for) your organization.

Warning: If the WorkGroup assignation of an Instrument is changed, all settings and operators will be cleared from the Instrument and new settings sent based on the new WorkGroup.



General Settings

Instrument Name * REJH-32765-00569

WorkGroup * Unassigned

Serial Number REJH-32765-00569

LumiraDx Wireless Id REJH-32765-00569

Software Version 1.2.0.1094dee

Hardware Version 5.4

Apply Changes

A prompt will ask the User whether any test data should be deleted from the Instrument when changing WorkGroups or whether the test data should be kept.

Warning: Selecting 'Delete Data and reboot the Instrument' means that test data will only be visible in Connect Manager.

6. Tap 'Apply Changes'.

Note: The WorkGroup menu will be hidden for organizations that are managing Instrument Operators through a middleware provider.

4.4 Test Results

Patient Test results and Quality Control test results can be viewed for each Instrument in your organization. Results can also be exported to a .CSV file if required.

1. From the Instrument page select the action menu  for the Instrument whose test results you want to view, and select 'Test Results'.

NAME	SERIAL NUMBER	STATUS
REHH-32765-00553	REHH-32765-00553	Online

2. Select date range for when the tests were performed.
3. Select 'Test Type' to filter by Test type.
4. Tap on any Test result to view further details of that test.
5. Tap 'Export' to send the list of results to a .CSV file

TIME OF TEST	TEST TYPE	STATUS
Aug 27 2020 6:24pm	SARS-CoV-2 Ag	Accepted >
Aug 27 2020 6:06pm	SARS-CoV-2 Ag	Accepted >
Aug 27 2020 6:04pm	SARS-CoV-2 Ag	Accepted >

The following warning will appear as a pop-up on screen.

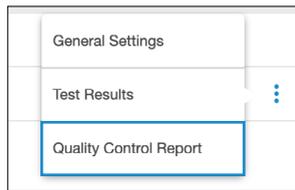
Warning: All data and information is displayed for viewing purposes only. The user acknowledges that any exportation of the data from the Connect Manager display function may result in corruption of that data. The user, on behalf of the Organization, shall accept sole responsibility for the use of any data or information extracted from the display function.

Note: Organizations managing the LumiraDx Platform through a middleware provider may choose to disable Test results being sent to Connect Manager. In this case the 'Test Results' option will not be available from the Instruments page in Connect Manager.

Quality Control Reports

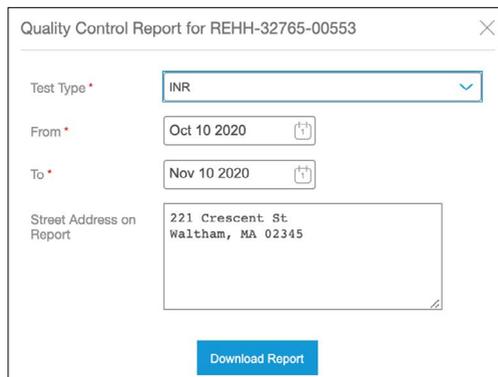
A PDF report of Quality Control Tests can be produced for each Instrument.

Tap 'Quality Control Report' from the Instrument action menu.



Select the Test Type, date range and optionally enter the address of the testing location.

Tap 'Download Report' to create a PDF of the Quality Control Report.

A screenshot of a form titled 'Quality Control Report for REHH-32765-00553'. The form contains the following fields: 'Test Type' with a dropdown menu showing 'INR'; 'From' with a date field 'Oct 10 2020' and a calendar icon; 'To' with a date field 'Nov 10 2020' and a calendar icon; and 'Street Address on Report' with a text area containing '221 Crescent St, Waltham, MA 02345'. At the bottom of the form is a blue button labeled 'Download Report'.

4.5 Personal Settings

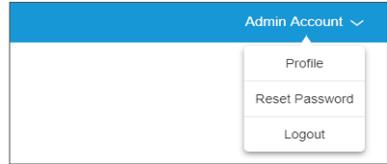
Updates to name, contact information, and password can be made.

To update your personal information:

1. Login to Connect Manager.
2. In the top right corner of the page tap your Name and select "Profile" from the drop-down menu.
3. Edit all of the relevant profile information fields:
4. Tap 'Save Profile'.

To change your password:

1. Login to Connect Manager
2. In the top right corner of the page tap your Name and select "Reset Password" from the drop-down menu.
3. Enter 'Current password' and 'New password' in the required fields. See section 5.2 for password requirements.
4. Tap 'Update Password'.

A screenshot of a "Profile" form. The form is titled "Profile" and has a close button in the top right corner. Under the heading "Personal Information", there are several input fields: "Username" (with the value "mbooth"), "Email" (with the value "First.Last@company.com"), "Title" (empty), "First Name" (with the value "Admin"), "Last Name" (with the value "Account"), "Initials" (with the value "AA"), and "Language" (with the value "English" and a dropdown arrow). A blue "Save Profile" button is located at the bottom right of the form.A screenshot of a "Reset Password" form. The form has a close button in the top right corner. It contains three input fields: "Current Password" (with masked characters "*****"), "New Password" (with masked characters "****" and a red warning icon), and "Confirm Password" (with masked characters "*****"). A "Password requirements" popup is overlaid on the form, listing the following rules: "At least 8 characters in length" (marked with a red X), "At least one number" (marked with a green check), "At least one lowercase letter" (marked with a green check), "At least one of these special characters: [-_!]" (marked with a green check), "At least one uppercase letter" (marked with a green check), "Does not use unsupported characters" (marked with a green check), and "Does not match your previous passwords" (marked with a green check).

4.6 Organization and Quality Control Settings

Organization administrators can update setting for the whole organization from the settings menu.

Organization settings

Tap 'Organization Settings' to update the time zone and contact details for the organization.

Once the settings have been updated tap 'Apply Changes'.

Southgate Hospital Settings

Region	United States
Language	English
Time Zone *	(GMT-05:00) Eastern Time (US & Canada) ▼
Contact Name *	Organizational Administrator
Contact Email *	administrator@yourorganization.org
Contact Phone *	5551234567

[Apply Changes](#)

Quality Control Settings

Quality Control

 The quality control policy can be overridden at the workgroup level.

Quality Control	Mandatory ▼
Quality Control Policy *	By Lot ▼
Policy Interval	<input checked="" type="checkbox"/> <input type="checkbox"/>
	<input type="text" value="20"/> <input <span="" type="text" value="Days"/> ▼
Require for each new lot	<input checked="" type="checkbox"/> <input type="checkbox"/>

[Apply Changes](#)

The following features can be configured to determine the Organization's Quality Control Policy.

Quality Control

- **Off**
- **Mandatory** – If the Quality Control policy has expired users are unable to perform a patient test, until a Quality Control Test has been performed with a status of PASS.
- **Advisory** – If the Quality Control policy has expired a warning is displayed on the Instrument. Users can acknowledge the warning and proceed with testing.
- **Mandatory with Override** – If the Quality Control policy has expired, users are required to either run a Quality Control Test or override the expired Quality Control policy and run a patient test by entering a comment to explain the reason for the override.

Quality Control

i The quality control policy can be overridden at the workgroup level.

Quality Control

Require for each new lot

- ✓ Off
- Mandatory
- Advisory
- Mandatory With Override

Apply Changes

Policy

- **By Lot** – Users will be required to perform a Quality Control test when using a new Test Lot on an Instrument for the first time.
- **By Type** – Users will be required to perform a Quality Control test when using a new Test Type on an Instrument for the first time

Policy Interval

Set a Policy Interval by moving the 'Policy Interval' slider to 'on'. Enter a number and select 'Tests' or 'Days' to determine how frequently a Quality Control test is required for each Lot or Test Type on each Instrument.

Require for each new lot

Use the slider to determine if a Quality Control test should be required for each new lot of Test Strips. This defaults to 'on' when the Policy is set to By Lot. The setting is editable when the Policy is set to By Type.

Quality Control Policy by WorkGroup

Each WorkGroup is set to the Organization's Quality Control policy by default. The settings can be overridden for an individual WorkGroup within the WorkGroup settings. A WorkGroup level Quality Control Policy can be set even if the Organization Quality Control is set to 'Off'.

← WorkGroups

Emergency Room

Users	Instruments	Settings
-------	-------------	----------

Name *

Description

Quality Control

Override Organization's Quality Control Policy

Quality Control

Quality Control Policy *

Policy Interval

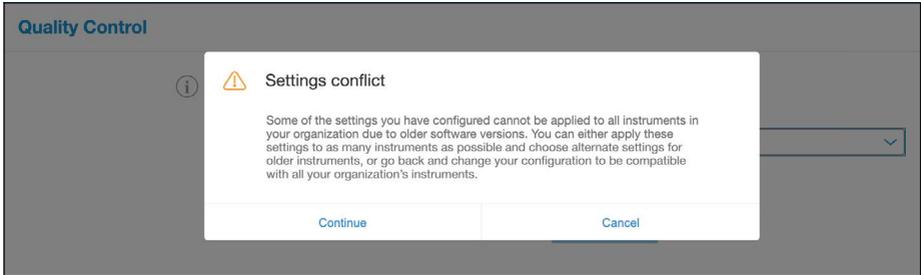
Require for each new lot

Note: If the organizations Quality Control policy is being managed by a middleware provider, the Quality Control settings in Connect Manager will be 'read only'. The user will be able to view the Quality Control policy settings sent by the middleware provider but will not be able to edit them within Connect Manager.

Mixed Instrument software versions

If some Instruments in the Organization are running on an old software version, they may not be compatible with all the configurable settings in Connect Manager. In this case, Connect Manager will display a message to highlight that settings are not supported on all Instruments and what steps can be taken to resolve the issue.

Quality Control Policy example



The screenshot shows the 'Quality Control' configuration page. At the top, there is an information icon and the text: 'The quality control policy can be overridden at the workgroup level.' Below this are several settings:

- Quality Control:** A dropdown menu set to 'Mandatory With Override'.
- Quality Control Policy*:** A dropdown menu set to 'By Lot'.
- Policy Interval:** A toggle switch is turned on, with a text input field containing '20' and a dropdown menu set to 'Days'.
- Require for each new lot:** A toggle switch is turned on.

A warning box titled 'Quality Control support warning' contains the text: 'The Quality Control Policy that you have selected cannot be applied to all instruments in your Organization. Please select a fallback setting which shall be applied to all remaining instruments.'

Below the warning box are two sections:

- PARENT SETTINGS:** A link that says 'Applies to the 1 instrument running the latest software version'.
- FALLBACK SETTINGS:** A dropdown menu set to 'Off'.

Further down, there are sections for 'QUALITY CONTROL POLICY' (set to 'By Lot'), 'POLICY INTERVAL' (toggle on, '20', 'Days'), and 'REQUIRE FOR EACH NEW LOT' (toggle on).

At the bottom right of the page is a blue button labeled 'Apply Changes'.

User training example

Edit User ✕

Username *

Email *

Title

First Name *

Last Name *

Initials

Language * ▼

Connect Manager Roles ▼

Instrument Roles ▼

Instrument Workgroups ▼

Enforce instrument user training expiry

Training valid until * 📅

[Apply Changes](#)

5. Miscellaneous

5.1 Logging in to Connect Manager

To login to Connect Manager:

1. Either:
 - Open the Connect App on your mobile device; or
 - Using a web browser, navigate to connect.lumiradx.com.
2. Enter the organization access code if accessing Connect Manager for the first time.
Note: Organization Access code is only needed for first time visitors. The next time you visit this site you will access the login screen directly.
3. Enter 'Username' and 'Password' in the relevant fields.
4. Tap 'Login'.

To reset your password:

1. Either:
 - Open the Connect App on your mobile device; or
 - Using a web browser, navigate to connect.lumiradx.com.
2. Tap 'Forgot your password?'
3. 'Email' – enter your email address. A temporary validation code will be sent to your email address.
4. Set your new password
 - 'Email' – enter your email address.
 - 'Validation Code' – enter the temporary validation code sent to your email address.
 - 'New Password' – enter your new password.
 - 'Re-enter Password' – enter your new password.

5.2. Username and password requirements

Username requirements:

- Maximum username length is 20 characters
- Username must be unique to all other users in the organization
- Not case sensitive

User Password requirements:

- Case sensitive
- Minimum length of 8 characters
- Requires at least 1 numeric character
- Must contain a special character (allowable characters are -, . /)
- Requires at least one lower case character
- Requires at least one upper case character
- After 10 failed attempts, the user will be temporarily locked out of Connect Manager for 30 minutes. The Connect Manager Organization Administrator should be contacted if password reset is needed.

5.3. Application updates

The LumiraDx Connect App updates automatically through the phone's app store. The web version of the app also updates automatically and requires no action from your organization.

6 Customer Services

For product and connectivity support please contact LumiraDx Customer Services at customerservices@lumiradx.com.

For your local customer services phone number please visit the customer services page at lumiradx.com.

7 Security

- LumiraDx provides and enforces security and data protection within the Connect system architecture in addition to policy and process. To do this, we make the following precautions with regards to data protection:
- All data in-transit or at rest in the system is encrypted to FIPS 140 standards.
- Endpoints and protocols employ data authentication and integrity mechanisms to prevent hacking.
- End-to-end encryption is used between secured endpoints to protect data when traveling over public or unsecured networks.
- Data travels through the system de-identified until it reaches the Electronic Health Record where it can be re-identified to a patient.
- Identifiable and pseudonymized data is only stored where information security and data protection controls are compliant with the legislative and regulatory requirements relevant to the geographic region of the patient.
- Only fully anonymized data is sent to LumiraDx for performance monitoring and analysis.

7.1. General Data Protection Regulation (GDPR) Compliance

Along with its security protections, LumiraDx has ensured that it complies with every principal of GDPR.

8 Privacy Notice

An administrator or user using LumiraDx Connect Manager and EHR Connect for the first time will be required to read and accept the following privacy notice.

Your Consent to this Privacy Notice

By using these applications, you signify that you agree with the terms of our current Privacy Notice detailed here. If you do not agree with any term in this Privacy Notice, please do not use these applications.

Personal information we collect

We may collect the following types of personal information from you when you use LumiraDx services or products:

1. Account details: when you use the application, an account will be created for you by LumiraDx or by your organization's administrator. The account will include a user name, email address, password, work group and full name.
2. When you use the application: We will record details of application usage to maintain an audit trail. This will include information relating to where the application is used (which organization), when you used the application and what tasks you performed using it.
3. Patient details. To ensure the patient can be identified and the correct test results associated with the patient in your Electronic Health Record.
4. Test results. What tests were performed on which patients and the results when using EHR Connect.

What we use your personal information for?

Purpose:

- Provide our services to you and maintain your account.
- Ensuring users have access to information relevant to their role and only to their role.
- Ensure regulatory compliance.
- Data analytics and statistical research to help us better understand how our products are used.
- Investigating misuse of your account, fraud and debt collection.

We may anonymize and aggregate any of the personal information we hold (so that it does not directly identify you). We may use anonymized and aggregated information for purposes that include testing our IT systems, for research, data analysis, improving and developing our products and services.

Who we share your personal information with?

We may share personal information with the following parties:

- Companies in the same group of companies as us: for the purpose of providing a service to you and understanding our use of our products and services.
- Other service providers and advisors: such as companies that support our IT or help us analyze the data we hold.
- The Government or our regulators: where we are required to do so by law or to assist with their investigations or initiatives for the energy industry.
- Police and law enforcement: to assist with the investigation and prevention of crime when legally required.

We do not disclose personal information to anyone else except as set out above. We may provide third parties with aggregate statistical information and analytics about users of our products and services, but we will make sure no one can be identified from this information before we disclose it.

Transferring your personal information internationally

The personal information we collect may be transferred to and stored in countries outside of the European Union. Some of these jurisdictions require different levels of protection in respect of personal information and, in certain instances, the laws in those countries may be less protective than the jurisdiction you are typically resident in. We will take all reasonable steps to ensure that your personal information is only used in accordance with this privacy policy and applicable data protection laws and is respected and kept secure.

How long do we keep personal information?

We will keep your personal information for a period determined by national guidelines and regulatory requirements.

Your rights in relation to personal information

You have the following rights in relation to your personal information whether you are a user of LumiraDx Connect services as healthcare professional or a patient:

- the right to be informed about how your personal information is being used;
- the right to access the personal information we hold about you;
- the right to request the correction of inaccurate personal information we hold about you;
- the right to request the blocking or deletion of your personal information where the processing does not comply with applicable data protection laws.

To exercise any of the above rights, or if you have any questions relating to your rights, please contact us by using the details set out in the 'Contacting us' section below.

If you are unhappy with the way we are using your personal information you can also complain to the UK Information Commissioner's Office or your local data protection regulator. We are here to help and encourage you to contact us to resolve your complaint first.

Changes to this notice

We may update this privacy notice from time to time. When we change this notice in a material way, we will update the version date at the bottom of this page. For significant changes to this notice we will try to give you reasonable notice unless we are prevented from doing so. Where required by law we will seek your consent to changes in the way we use your personal information.

Contacting us

Full details of the LumiraDx privacy policy can be found on our website lumiradx.com. In the event of any query or complaint in connection with the information we hold about you, please email us at: privacy@lumiradx.com

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9 Legal Notices

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ART-00300 Rev4

For product and connectivity support please contact LumiraDx
Customer Services at customerservices@lumiradx.com