Cepheid C360



Administrative Features Operator Manual



Nonmedical-device software system for disease surveillance

301-8332, Rev. J December 2023

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1 Introduction

This chapter introduces the *Cepheid C360 Administrative Features Operator Manual* and provides a brief description of the administrative features of Cepheid C360.

1.1 About Cepheid C360 Administration

Cepheid C360 is a web-based software application for administering Cepheid[®] systems and visualizing aggregated medical test data produced by Cepheid instruments.

This manual describes the following administrative functions of Cepheid C360.

- Administration of user accounts and passwords for logging in to Cepheid C360.
- Creation of laboratories.
- Assignment of user roles that restrict or permit institution personnel access to Cepheid C360 features depending on their job functions.
- Setting institutional policies that control a few overall settings for Cepheid C360
- Logging events taking place on all Cepheid instruments in the institution, including errors, routine maintenance tasks and other useful information.
- Maintaining information about instruments, laboratories and users that describes their relationships and allows patient test data to be recorded in a structured, traceable way.

1.2 Related Publications

For information about topics related to Cepheid C360, see the following publications.

For this topic:	See this publication:
The data-visualization features of Cepheid C360	Cepheid C360 Data-Visualization Features Operator Manual
Connecting instruments to Cepheid C360	C360 Sync Installation and Networking Operator Manual
Operating and administering the GeneXpert Xpress System	GeneXpert Xpress System User's Guide
Operating and administering GeneXpert Dx systems	GeneXpert Dx System Operator Manual
Operating and administering the GeneXpert Infinity System	GeneXpert Infinity System Operator Manual
Operating and administering the GeneXpert Edge System	GeneXpert Edge System User's Guide

1.3 Technical Assistance

Before contacting Cepheid Technical Support, collect the following information:

- Product name
- Instrument serial number or numbers
- Error messages (if any)
- Software version and, if applicable, Computer Service Tag number

United States Technical Support

Telephone: + 1 888 838 3222 Email: techsupport@cepheid.com

France Technical Support

Telephone: + 33 563 825 319 Email: support@cepheideurope.com

Contact information for other Cepheid offices is available on our website at www.cepheid.com/en/CustomerSupport.

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Telephone: + 1 408 541 4191 Fax: + 1 408 541 4192 www.cepheid.com This chapter summarizes the purpose of Cepheid C360 and introduces the features and interface of the Cepheid C360 administrative toolset.

Note Cepheid C360 is a supplemental information-management web application that functions as an IT application. It is not involved in the diagnosis, treatment or monitoring of patients.

Your institution is responsible for ensuring that the uploading of data to the Important Cepheid C360 server complies with applicable laws and regulations, including those concerning privacy and data-protection.

In Cepheid C360, an institution is a single organization that can have a number of labs, institution administrators, laboratory administrators, and GeneXpert[®] Instrument Systems linked to their labs.

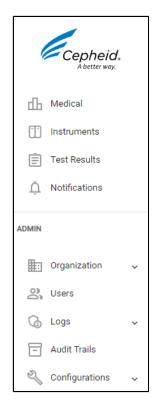
Note A supranational institution is an organization, such as the World Health Organization (WHO), that can send data-sharing requests to other institutions and, upon acceptance of such requests by the institutions, perform epidemiological interpretation of the aggregated data based on the data shared.

2.1 Cepheid C360 Interface Overview

In Cepheid C360, a column runs down the left edge of the screen. It displays the datavisualization tools near the top, and the administrative tools further down in the column.

The top-level items for data-visualization are **Medical**, **Instruments**, **Test Results** and **Notifications**. The data-visualization tools are explained in the *Cepheid C360 Data-Visualization Features Operator Manual*.

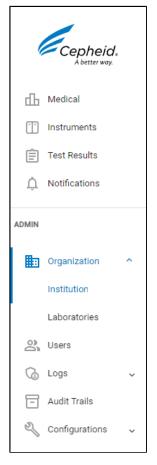
The Cepheid C360 administrative tools are located under the word **ADMIN** and are grouped into **Organization**, **Users**, **Logs**, **Audit Trails**, and **Configurations**. This operator manual explains the administrative tools and their menus.



2.2 The Cepheid C360 Administrative Toolset Interface

The **ADMIN** area includes five items, all of which open to provide search or configuration options. Some administrative items include several menus.

- The **Organization** item includes the **Institution** and **Laboratories** menus. They provide tools to configure and modify the institutions and laboratories in the organization. Note that the **Institution** menu displays only your institution. It is there for use by Cepheid Technical Support.
- **Users** is where administrators create or search for Cepheid C360 users, assign users to labs, disable or delete accounts, and perform other tasks affecting institution personnel.
- **Audit Trails** provides detailed information about what actions each Cepheid C360 user performs.
- The **Configurations** item includes **Registration Codes**, **Mobile Devices**, **Data Collection Policies**, and **Sharing Requests** menus. These tools are for an administrator to generate and manage registration codes that connect instrument systems to the Cepheid C360 system, configure what data Cepheid C360 collects from the instruments, and manage sharing requests between institutions.



Each of these tools is described in detail in this operator manual.

Note

Not all menu items are visible to all Cepheid C360 users. Access is based on the role assigned to each user in the Cepheid C360 system.

2.3 Administrative Toolset Tables

When using the Cepheid C360 administrative tools, the table view is generally where you access detailed information about anything and initiate necessary tasks. For example, under **Organization**, in the **Laboratories** table, you can search, filter and sort the list of labs, and export the list as a CSV file. Click an existing lab in the list to open its record and view or modify details about it, or click **New Laboratory** to create and configure a new lab. The search and filter tools available with each table are appropriate for the information the table displays. For example, the **Test Result Logs** table can be filtered by test GUID, instrument and result, among other settings, while the **Users** table can be filtered by lab, user role and related settings.

Search and Filter Data

To search and filter data, look for the pull-down lists that generally appear above the column headers in the table itself. The search and filter menus vary, depending on the type of data in the table.

Search			<u>ل</u>
Institution CEP Medical Center	1 West 👻 Identifier Filter by identifie	er Filter by name	9
Identifier	Name ↑		
locitanei	Name p	Institution	Address
MED1-WEST-MOB	CEP Med 1 West Mobile Lab	CEP Medical Center 1 West	Address 9680 W Burnside St Portland Oregon USA
		CEP Medical Center 1 West	

Sort Data

Some tables' column headers are active, so that clicking one sorts the table by the data in that column. In the example shown below, the white arrow next to **Name** indicates that the table is currently sorted by name. The pale arrow next to **Email** appears when the mouse hovers over that column header and indicates that the table could be sorted on that value instead. Not all columns in all tables can sort data.

The search and filter menus for many Cepheid C360 tables include a field for selecting Important the institution, but institution personnel only have access to data from their own institution. The institution field is there for the use of Cepheid Technical Support.

Username First Last Name ↑ Email ↑ Phone Institution Laboratory Role	Status
--	--------

Download Data

To determine whether a table can be exported, look for the **Download CSV** icon, which is usually located near the top right corner of the screen.



Search, filter and sort the table to prepare the data you need. Then click the icon to generate a CSV file. On the **Test Results** screen in the Data-Visualization toolset, multiple CSV files can be stored in a cache until you are ready to download and save them. In all other cases the software opens a **Save** dialog immediately.

Note The CSV format is designed for import into spreadsheet, database and statistical software tools. In CSV files, commas separate each data point and paragraph breaks separate each row of data. Cepheid C360 can export up to 3,000 rows of a table as a CSV file. (The Test Results table in the data-visualization toolset can export up to 300,000 rows.)

Each section in this operator manual provides appropriate specifics about filtering, sorting and exporting tabular data.

2.4 Return to Previous Page

Navigating Cepheid C360 is straightforward. Some screens display the steps of your path through the interface, which you can retrace with a click.

< Institutions / Institution Details / Policies for CEP Medical Center 1 West

Because Cepheid C360 runs in a web browser, the browser's back arrow accomplishes the same thing and is available in all locations.

2.5 About Browser Variation

Because Cepheid C360 runs in a web browser, the exact appearance of the screen may differ slightly depending on which browser you use. However, the features and functions are identical in any browser.

Cepheid C360 is tested with the Chrome, Edge, and Firefox browsers. Cepheid does Important not test other browsers. Logging in to your Cepheid C360 system with another browser will display a warning message that the browser is not supported.

2.6 Cybersecurity

Cepheid C360 includes the following data-security and user-authentication safeguards:

- Data encryption during transport and at rest
- Strong password requirements
- Two-factor authentication
- Automatic logout after inactivity
- Timed lockout after failed logins
- Role-based access-control
- Audit logs that monitor user interactions

If you experience a cybersecurity event, contact Cepheid Technical Support.

2.7 Logging In

Follow these steps to log in to your Cepheid C360 account.

First Login

When your account was created, you should have received a Welcome email with your user ID and a link to your institution's Cepheid C360 server. Follow the instructions in the email to complete setting up your account.

1. Follow the link in the Welcome email.

Note The Welcome email link is valid for only 24 hours.

2. On the **Welcome to C360** screen enter a password that meets the requirements displayed under **Password requirements**.

To complete your accou security questions	t setup, please enter a password and selec	et two
Enter and confirm your r	ew password	
Password requirements		
 14 –128 characters 		
At least two lowerc	ase letters	
 At least two uppercent 		
At least two number At least two numbers		
	characters: (~!@#\$%^&*=+,./<>?;:[\\}) il or username address	
	ur 10 previous passwords	
New password *	ø	
	~	
New password is required		
New password is required Confirm password *	6	
	Q	
	ଷ	
Confirm password *		
Confirm password *		
Confirm password *		
		•
Confirm password *		•
Confirm password * Select and answer your Security question 1 *		
Confirm password *		-
Confirm password * Select and answer your Security question 1 *		*
Confirm password * Select and answer your Security question 1 *		•
Confirm password * Select and answer your Security question 1 * Security answer 1		
Confirm password * Select and answer your Security question 1 * Security answer 1 Security question 2 *		•
Confirm password * Select and answer your Security question 1 * Security answer 1		-

- **3.** Select two security questions under **Select and answer your security questions**. Provide answers for the questions that you will remember and that other people will not know.
- **4.** Click **Submit**. You will be transferred to the regular login screen. Enter your user ID and new password, and your institution's alias. We recommend that you bookmark the Cepheid C360 site.
- **Note** The institution alias is provided by Cepheid to the institution's administration and is included in the Welcome email.

Subsequent Logins

After your account is established, logging in to Cepheid C360 is similar to logging in to any system that uses two-factor authentication.

1. In a browser, open the URL for your institution's Cepheid C360 server.

Username * Institution_Admin	
Institution_Admin	
Password *	3
	Sign In
	Forgot password?

- 2. Enter your username and the password you created when you completed setting up your account. Passwords are masked by default. To see the password as you enter it, click the eye icon next to the **Password** field. Passwords are case-sensitive, while usernames are not.
- 3. Enter the alias for your institution.
- **Note** If you enter an incorrect password or alias, your login fails but the error message doesn't explain why.

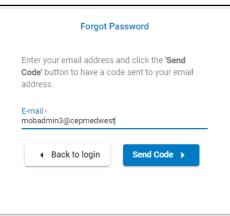
The login screen changes to display the **Code** field.

4. Look in your email or on your phone for a message from *Cepheid C360 team*. Enter the number provided in the **Code** field in the message and click **Login**.

Replace Forgotten Password

If you forget your password you can replace it.

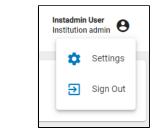
1. Click Forgot password? on the splash screen to open the Forgot Password screen.



- 2. Enter the email address associated with your Cepheid C360 account and click **Send Code**.
- 3. Look in your email for a message from Cepheid C360 team.
- 4. Enter the code provided in the message and click **Submit Code**.
- **5.** Create a new password. When changing your password during login, you do not set new security questions.

2.8 Logging Out

To log out of Cepheid C360, click the person icon next to your name, in the upper-right corner of the screen. When the menu displaying **Settings** and **Sign Out** opens, select **Sign Out**.



Note

Cepheid C360 logs you out without a confirmation prompt.

Cepheid C360 logs you out automatically under the following circumstances:

- There has been no activity for 15 minutes.
- The session has been active for more than 24 hours.
- The browser window running the Cepheid C360 session is closed.
- Your username and password are used to log in from another computer or from another browser on the same computer. This could happen if someone else logs in using your credentials, or if you log in from a second computer or browser.

2.9 Account Lockout

If you make three unsuccessful attempts to log in within 30 minutes, the account locks and remains locked for 30 minutes.

Note

This chapter explains how to perform necessary administrative tasks in Cepheid C360. It covers the following tasks.

- How to create institutions and laboratories.
- How to create users and assign them to appropriate roles.
- How to set institution policies.
- How to view lab and instrument audit trails.
- How to list instruments, labs and personnel.
- How to change users' passwords, delete or suspend user accounts, and add users in batches.
- How to configure registration codes for connecting instruments to the C360 server and link them to their institution.

3.1 Cepheid C360 Administration Setup

During the sales process, a representative at your institution provided information to Cepheid, including the following:

- The name of your institution
- The names of one or more laboratories in the institution
- The name, email address and phone number of the user who will fill the primary Institution Admin role in Cepheid C360

To provision your institution's order, Cepheid performed the following tasks:

- Entered your institution's information into Cepheid C360
- Created login credentials for the primary institution administrator
- Sent a Welcome email with login information to the primary institution administrator

Upon receipt of the Welcome email, the primary institution administrator should log in to Cepheid C360, verify the information entered by Cepheid, add laboratories if needed, add users as needed, and set the institution policy.

Note The Welcome email link expires after 24 hours.

3.2 Verifying the Primary Institution Admin Account

When Cepheid hands off the institution it has created, the first thing you, as the primary institution administrator, should do is ascertain that you can log in and that your account in Cepheid C360 is set up correctly.

- 1. Under **ADMIN** click **Users** and find your name in the list. Under the **Role** column it should specify *Institution admin*.
- Click your name. The User Details screen opens.

User	Institution
Username	Name
westadmin1	CEP Medical Center 1 West
First name CEPMedWest	
	Location 오
Last name	Multnomah - Oregon - United States
InstAdminOne	
E-mail	Supernational Institution
instadmin1@cepmedwest.com	No
Phone	
Role	
Institution admin	
Created	
2/16/22, 5:15 PM	
Last login	
3/6/22, 2:25 PM	

- **3.** Review the information. If anything is incorrect or incomplete, click **Edit**. The **Edit Details** screen opens.
- 4. Correct the information, then click **Save**.
- You cannot change the user role or the institution's name or location or whether it is aNotesupranational institution. If any of those fields are not correct, contact Cepheid Technical
Support.

3.3 Verify Institution Details

After Cepheid, based on specifications provided by the institution administrator, creates an institution in Cepheid C360, the administrator should verify that it meets the specifications.

1. Click Organization, then click Institution. The Institution Details screen opens.

Institut	ion
Mode	: 🔘 System Monitoring Only 🔘 Full
Name	
Instituti	on
Alias	
instituti	on01
	d identifier
instituti	on01
Display	name
Instituti	
🗌 Su	pernational
Locatio	n
Sweder	1
Assay o	vode set
Resync	Period (days):
2	
Max Da	ata Category Level : 🔿 Result 🔿 Analytes 🔿 Patient Demographics 💿 Patient Identif
Sh	ow Module Info
	cepts sharing re
🗸 Ena	able Disease Su

- 2. Review the name, alias, and supranational setting, as well as other controls on this screen such as whether to accept sharing requests. If Cepheid was responsible for setting up a lab at your institution, look for it in the **Laboratories** pane at the bottom of the **Institution Details** screen. You should also verify some other settings:
 - The resync period for your institution, that is, how frequently C360 Sync checks for test results that have not yet been uploaded to Cepheid C360.
 - Under **Max Data Category Level**, the level of detail about each test that the operator can configure data-collection policies to transfer from instruments to the Cepheid C360 database. The options range from simply whether the test returned a result, to what analytes it detected, to demographic data collected about the patient, or the patient ID.

Your institution is responsible for ensuring that the uploading of data to the
Cepheid C360 server complies with applicable laws and regulations, including those
concerning privacy and data-protection. Discuss this with Cepheid before your
institution is created in the Cepheid C360 system.

- Whether to display information about instrument modules.
- Whether your institution can be solicited by supranational institutions to share data. **Accepts sharing requests** means that your institution is visible to supranational institutions and can receive share requests; it does not mean that your institution has agreed to share data.
- Disease surveillance and the **Medical Dashboard**. Disease surveillance must be active for Cepheid C360 to have access to the raw data returned by instruments before the GeneXpert software cleans up the test-results data.

Note If your institution was configured without enabling Enable Disease Surveillance and Medical Dashboard, the Medical Dashboard menu will not be visible. For details about disease surveillance and the Medical Dashboard, see the Cepheid C360 Data-Visualization Features Operator Manual.

Note If any of these settings are incorrect or you don't understand their impact, contact Cepheid Technical Support. Institution administrators cannot adjust settings on the Institution Details screen—only Cepheid Technical Support can make corrections.

3.4 Adjusting Your Cepheid C360 Setup

This section explains how to adjust a few basic settings of your Cepheid C360 account.

3.4.1 Changing Basic User Settings

Follow these steps to change details on the **User Settings** screen.

1. Click the person icon, then click **Settings**.

The User Settings screen opens, with two buttons: Change password and Edit.



2. Click Edit.

The email address and the phone number fields become editable.

Institution Details	Institution admin
	Change password Edit
Login information	
User Inst_Admin_role	
E-mail instadmin4@cep.com	
Phone	
Alias MainInstitution01	
Role Institution admin	
Last login 5/15/23, 4:31 PM	

Note

The only fields on the **User Settings** screen that can be edited after your account is set up are the email address and the phone number.

3. Make any required changes, then click **Save**. Click **Cancel** instead to revert to the previous email and phone.

3.4.2 Changing Security Settings

Follow these steps to change your account password and security questions.

1. Open the User Settings screen, then click Change password. The Change Password screen opens.

Please enter your current password to change your password and/or security questions.
Current Password
New Password
Set a new Password
Password requirements
 14 -128 characters At least two lowercase letters At least two uppercase letters At least two numbers At least two special characters: (~!@#\$%^&*=+,./<>?;:[\\}) Cannot be your email or username address Cannot be one of your 10 previous passwords
New password
Confirm password
Security Questions
Set your security q
Security question 1 What was your childhood nickname?
Security answer 1
Security question 2 What is your oldest sibling's middle name?
Security answer 2

- 2. Enter your current password.
- **3.** Enter a new password, following the required password format shown on the screen. Confirm the new password on the second line.
- 4. Select or update one or both security questions from the pop-ups. Provide answers for the questions that you will remember and that other people will not know.
- 5. Click Save.

3.5 Overview of the Cepheid C360 Configuration Settings

This section describes how to configure general institution policies, set data-collection policies, and manage instrument-system registration codes.

3.5.1 Setting Cepheid C360 Institution Policies

The institution policy settings consist of a few general policies for how the institution is to operate. Only a user with the Institution Admin role can set institution policies.

- 1. Click Organization, then click Institution. The Institution Details screen opens.
- 2. Click Institution Policy.
- 3. In the Institution Policy screen, click Edit.
- 4. Use the table as a guide to make your policy choices.

eneral settings			
Automatically disable user account after	uavs mactive	365	
Enable weaker password for lab assistan	ts 🗌		
Allow concealing a result from view (on a	pplicable assays	s only)?	
Allow remote instrument software update	es?		
Bundle Download Code (BDC) required	\checkmark		

Policy	Action
Automatically disable user account after days inactive?	Select to enter how many days an account can go without the user logging in before the account is disabled. The default value and maximum is 365 days.
Enable weaker password for lab assistant users?	This feature is no longer used.
Allow concealing a pathogen result from view?	Select to allow instrument operators to avoid displaying some results generated by an assay. This can prevent positive results of an endemic pathogen from overwhelming other positive results. (Not available for all assays or all instruments.)
Allow remote instrument software updates?	Select to allow software updates to be delivered over the internet. The default is selected.

Policy	Action
Bundle Download Code (BDC) required	If Allow remote instrument software updates? is selected, the bundle download behavior is determined as follows:
	 If checked in Full mode, the Institution Admin receives the bundle code in the Download Center feature. If unchecked in Full mode, no bundle code is sent. If checked in SMO mode, the Business Administrator receives the bundle code in the Download Center feature. If unchecked in SMO mode, no bundle code is sent.
	A bundle code can be used by an institution to download software or ADFs. The institution can determine if they require a bundle code to be entered prior to downloading software or ADFs. The bundle code expires in 48 hours.

3.5.2 Setting Data-Collection Policies

Data-collection policies are useful to narrowly target specific information. For example, you can set up a data-collection policy to extract just the results of one assay conducted in a particular lab or on a particular instrument. Two data-collection policies could gather the same data from the same instruments but return different results based on different **Max Data Category Level** settings.

Data-collection policies are set up by Cepheid Technical Support or institution admins, usually at the request of an epidemiologist, to manage what information generated by instruments is presented in Cepheid C360 for data-visualization purposes. Supranational institutions do not receive data gathered by nonsupranational institutions' data-collection policies.

- Under Configurations, click Data Collection Policies. The Data Collection Policies screen opens, showing a list of your institution's currently active data-collection policies.
- 2. To create a new data-collection policy, click New Data Collection Policy. The New Data Collection Policy screen opens. The Data Collection Policy Enabled slider defaults to being active. To create and implement a data-collection policy, leave the slider as is. You can set up and deploy a data-collection policy, then later make it temporarily inactive by shifting the slider to Disabled.

Data Collection Policy Enabled	
Name *	
CEP West broad spectrum data	
Start date •	
3/6/2022	
nstitution *	
CEP Medical Center 1 West	

3. In the **Data Collection Policy Details** pane, give the policy a descriptive name and select the date when you want the policy to go into effect. The **Institution** field defaults to your institution.

When you complete entering information in the **Data Collection Policy Details** pane, the **Rules** pane opens just beneath it.

☐ U If che	ata Category Level: Result Analytes Patient Demographics Patient Identifier load datagrams cked, datagram information will be included with each test, which provides additional information at the cost of used bandwidth usage
🗆 S	ample ID
Assay	5*
Fields	

Note The **Patient Identifier** option may not be available for all customers as described in the provided user rights permissions document.

- 4. Fill out the fields in the **Rules** pane.
 - a) Select the level of data to collect.

The choices are constrained by the setting in the Institution Details screen.

b) Check **Upload datagrams** to include datagrams with each test result.

Note Datagrams are a tool used by Cepheid Technical Support to monitor the integrity of data transmissions between instruments and the Cepheid C360 server. We recommend uploading datagrams except in situations of very limited bandwidth.

c) Check **Sample ID** if you intend to collect that information from each test.

Note The **Sample ID** setting may not be visible, depending on how your institution was configured when first created by Cepheid.

- d) Click the line under Assays to open the list of assays. Choose Select all or click to select the assays you want to include. To add individual assays you must click the field line repeatedly to make the menu pop up. To remove an assay after you select it, click the small "X" next to the assay name. To remove them all, click Select none.
- e) From the Fields pop-up menu, choose Select All, or click to select one or more of the listed options. To select individual fields, click the field line repeatedly to make the menu pop up. To remove a field after you select it, click the small "X" next to the field name. To remove them all, click Select none.

Note: When you enter a patient's age, the **Age group** or **Age group CDC** (whichever is active based on the setup in C360 Sync) assigns the patient to standardized age categories for epidemiological purposes.

f) Click Add Rule to append additional rules to the data-collection policy.

Max Data Categ 🗸 Upload data		ult 🔿 Analytes (Patient Demograp 	hics 🧿 Patient Identifier
f checked, data ncreased band		l be included with ea	ch test, which provide	s additional information at the cost
🗸 Sample ID				
Assays*				
Xpert C. diffici	e 🙁 Xpert Flu/	RSV XC (Flu only) 🤞	3 Xpert Flu/RSV X	C (Full) 🙁 Select Assays
Select none				
Fields				

5. Beneath the **Rules** pane, in the **Applies To** pane, narrow down the results by entering a location, one or more labs, or even specific instruments. The process is similar to adding assays to the data-collection policy.

elect location	
Multnomah - Oregon - United States 🛞 Select Location	Select none
ect laboratories	
CEP Med 1 West Mobile Lab Select laboratories	Select none

Note A data-collection policy can have as many rules as your institution has assays.

6. Click Save.

The new policy becomes operational and is added to the list of data-collection policies.

7. To modify a data-collection policy, click the one of interest in the **Data Collection Policies** screen.

The **Data Collection Policy Details** screen opens. You can change all of the policy's settings on this screen in the same way you created them.

8. To delete a data-collection policy, open it from the **Data Collection Policies** screen. At the bottom of the **Data Collection Policy Details** screen click **Delete**.

3.5.3 Configure Instrument Registration Codes

Cepheid instruments require a registration code so that C360 Sync can connect the instruments to Cepheid C360. Follow these steps to generate and manage the registration codes. For more information on Cepheid C360 Sync see the C360 Sync Installation and Networking Operator Manual.

1. Under the Configurations menu click Registration Codes.

The table of registration codes opens.

Registration Codes		CEPM	/ledWest InstAdmi Institution a	nOne 😫
			New Registr	ation Code
Name	Code	Institution	Applicable	Usage
	5cc04672-9e51-463d-8e09-338d2f2f7d31	CEP Medical Center 1 West		4 / 50
West Med 1 Reg Code Aug-Dec	e5148bd6-18b6-4ff2-ba5d-2bcac6e11e85	CEP Medical Center 1 West		0 / 50
	Items per pa	ge: 25 💌 1 - 2 of 2	< <	$\rightarrow \rightarrow$

Under the **Applicable** column in the table, registration codes displaying a white checkmark on a green background are active. Those displaying a white bar on a gray background are expired or deleted.

2. Click New Registration Code above the table of registration codes. The New Registration Code screen opens.

< Registration Codes / New	Registration Code
Active	
Name	
Expiration date *	i (;
Max usages * 50	(i)
Institution	
Please select the institution that you wa	int to create the Registration Code for
Institution * CEP Medical Center 1 West	*
	Generate Cancel

3. Give the new code a recognizable name. Set an expiration date in the **Expiration** date field and in the **Max usages** field specify how many Cepheid C360 Sync clients can use the registration code.

								.
Note	Hover over the	information	icons for	details on	the Ex	piration	and Max	usages fields.

Note The expiration and maximum usage settings are for security purposes.

- 4. Click Generate. The new code is created and appended to the end of the list in the Registration Codes table.
- **Note** The **Registration Codes** table cannot be sorted, filtered or exported.
 - 5. To modify a code's expiration date or usage limit, scroll through the list to find the code, then click to open it. Make the changes required, then click **Save**.

- 6. To enter the registration code when registering a new instrument in Cepheid C360 Sync, you can copy it from the **Code** field to the Windows[®] Clipboard and then paste it into Cepheid C360 Sync.
- 7. To delete an expired code, open it in the **Registration Codes** table, click **Delete**, then in the confirmation dialog click **Yes**.

3.6 About Updating ADFs and Instrument Software

Cepheid occasionally releases updated instrument software and new or updated assay definition files (ADFs). Based on your institution's discussions with Cepheid Technical Support, bundles of new software or updates will be prepared for your institution and delivered through C360 Sync, the software that manages communication between your instrument and the Cepheid cloud servers.

Downloading and installing ADFs and instrument software bundles from Cepheid C360 eliminates the need to receive and manage software distributed on CDs or DVDs. It allows Cepheid to ensure that your institution is using the optimal software for your instruments and workflow. Generally, it is the responsibility of an institution admin to download and install update bundles, though some of this task can be delegated to a laboratory admin. We recommend that the institution admin collaborate on this process with a system admin.

For detailed instructions on using C360 Sync to download and install bundles see the C360 Sync Installation and Networking Operator Manual.

3.7 Managing Labs

This section describes the tasks required to administer laboratories in Cepheid C360. The tasks include the following:

- Creating labs
- Assigning personnel and instruments
- Editing lab information
- Deleting labs

Note

A lab in Cepheid C360 does not have to be a specific physical space or a division of the organization. You can create a lab in Cepheid C360 and assign instruments and personnel in whatever way you find convenient or necessary. A lab can be a temporary grouping, as needed to support a short-term project, or a permanent administrative unit. A lab can consist of instruments and personnel gathered in one room in a healthcare setting, or combined from different settings scattered across the globe.

3.7.1 Adding a Lab

Follow these steps to enter a lab at your institution into the Cepheid C360 system.

- 1. Under ADMIN, click Organization, then click Laboratories. The Laboratories screen opens.
- 2. Click **New Laboratory** near the top right corner of the screen. The **Add New Laboratory** screen opens.

< Laboratories / Add New	w Laboratory	
Laboratory information		
Name *		
Identifier *		
Type * Stationary	*	
Institution *	•	
Laboratory location		
City *		
State *		
Country *		
Region *		
La calla de	í	
Location *		

- 3. Fill in the fields in the Laboratory information and Laboratory location panes.
 - For **Identifier**, define a brief label for the lab that colleagues will recognize. Lab identifiers can be up to 255 characters long, but we recommend using short, obvious identifiers.
 - Under **Type**, indicate whether the lab is mobile ("Ambulatory," such as a lab in a truck) or located in a healthcare facility ("Stationary").

Note The Location field defaults to the same location as the institution that the lab belongs to. In the United States, this is always a county. Different countries have different geographical subdivisions.

4. Click Save or Save and add another.

3.7.2 Verifying and Editing Lab Details

Follow these steps to view and modify the settings for a laboratory.

- 1. Under ADMIN, click Organization, then click Laboratories. The Laboratories screen opens, displaying your institution's labs in a list. The list can be sorted by identifier, lab name, or institution.
- Click the lab of interest. The Laboratory Details screen opens. It displays the same fields you filled out when creating the lab.
- **3.** Review the information on the **Laboratory Details** screen. Beneath the pane with information about the lab itself, there is another pane, called **Users**, with information about personnel assigned to the lab. The **Users** pane is closed by default. To open the list, click on it.

- Note You cannot edit personnel in the Users list on this screen or sort the table. However, you can export the list as a CSV file by clicking the **Download CSV** icon just above the column headings.
 - 4. If anything needs to be changed, click **Edit Laboratory**. Most fields on the **Edit Laboratory** screen can be modified. The institution and whether the lab is stationary or ambulatory cannot be modified, nor can the location once the lab has uploaded any data to the Cepheid C360 server.
 - 5. Click **Update** to save the changes, or **Cancel** to revert to the previous settings. Click **Delete** to delete the lab, but see additional considerations before deleting a lab.

3.7.3 Deleting a Lab

To delete a lab, select it from the **Laboratories** list, click **Edit Laboratory** in the **Laboratory Details** view, then click **Delete** at the bottom of the screen. When the confirmation dialog opens, click **Delete** again.

A lab cannot be deleted under any of the following circumstances:

- It has personnel associated with it.
- It has instruments assigned to it.
- **Important** It has produced test results and uploaded the data to the Cepheid C360 database.

You must remove personnel from the lab and ask Cepheid Technical Support to remove instruments before attempting to delete the lab. Only Cepheid Technical Support can remove instruments.

Once a lab has produced test results and uploaded the data to Cepheid C360 the lab cannot be deleted, but it is possible to remove the lab's personnel and instruments. Uploaded data remains in Cepheid C360 after the instruments that produced it have been deleted.

3.7.4 Viewing a Lab's Assigned Instruments

Find the instruments assigned to a specific lab by following these steps.

The **Review Instruments** button on the **Instruments** screen opens a list of newly installed or reinstalled instruments waiting to be approved. That is a separate function from searching for a lab's operational instruments. For more information on installing instruments, see the C360 Sync Installation and Networking Operator Manual.

1. Click **Instruments** near the top of the **Data-Visualization** tools in the column at the left side of the screen.

The **Instruments** screen opens.

- 2. From the **Model** pop-up menu at the top of the screen, select the instrument model or models, if desired.
- Click the Institution/Laboratory pop-up. Check the checkbox next to your institution name. The right-pointing arrow points down and the institution's labs appear below the

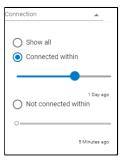
institution name. Each lab name is preceded by a checkbox.

4. Check the checkbox next to the lab of interest. Instruments assigned to that lab are listed in the table below the pop-up menus.

Note

here are 39 instri	uments to review								Review Instrumen
√odel: GeneXpert®	l, GeneXpert® II, GeneXpert® 👻		Institution/Lab	pratory			Connection	•	글는 Advanced
			123TestUserInstit		>	Î			
			ADF Inst	itution	>				
			Automat	ionInstitut	>				4
Connection	Name 🛧	Model		ital1		ion	Laboratory	Institution	Location
8	AnthemEdge	GeneXpe		Avi Hospital1	>	Demo	sk_sync	demoinstitution	Kweneng North
R	AviXpress	GeneXper		Cepheid		Demo	Avi Lab	Avi Hospital	Asotin
	AviXpress	GeneXper	t® Xpress	8765499999	Xr6.4.9	8_Demo	Avi Lab	Avi Hospital	Asotin
	CepheidInstInstrument	GeneXper	t® IV	2003004050	4.7b		CepheidLab1	Cepheid AB	West-Vlaanderen
	curieSyncInstrument	GeneXper	t® IV	20220887656			syncLaboratory01	synclnstitution01	Solna
R	curieSyncInstrument	GeneXper	t® IV	202208876677	4.7b		syncLaboratory01	synclostitution01	Solna
N	DONOT USE - Thach VM Apr12	GeneXper	t® IV	355717220412			Thach Lab 01	Thach Institution 01	Solna

5. With the **Connection** pop-up you can further narrow down the list by searching for instruments based on how much time has elapsed since they last connected to Cepheid C360.



3.7.5 Viewing a Lab's Assigned Users

Follow these steps to generate a list of users assigned to a lab.

- 1. Under ADMIN, click Organization, then click Laboratories. The Laboratories screen opens with the table in the lower pane listing the laboratories at the institution.
- 2. Click the laboratory of interest. The Laboratory Details screen opens.
- **3.** Scroll down and click the **Users** pane to display a table listing people assigned to the lab.

The list of people cannot be sorted, and clicking a name does not open a detail screen about the user. However, the list can be searched, and it can be exported to a CSV file by clicking the **Download CSV** icon above the table.

3.8 Managing Users

This section describes tasks required to manage user accounts. This includes the following tasks:

- Adding, deleting and disabling user accounts
- Changing, deleting and resetting passwords
- Editing user contact information
- Assigning user roles

3.8.1 Configuring Cepheid C360 User Roles

Before adding users to Cepheid C360, you must first understand user roles.

Every Cepheid C360 user is assigned a user account with a user role. User roles define access privileges, just like the access privileges you may have on your organization's computer network.

Access privileges control what parts of the Cepheid C360 interface users can see as well as the data they can access and the tasks they can perform. Limiting access to the required features and data has the following advantages:

- It simplifies the interface for some users.
- Users cannot accidentally change someone else's work.
- Users cannot see information they are not authorized to see or perform tasks they are not authorized to perform.

Cepheid C360 has the following roles:

- **Institution Admin**: A user with the Institution Admin role has the same privileges as a laboratory admin. In addition, an institution admin can edit, add and delete labs, add additional institution admin and laboratory admin users, and set institution policy.
- Laboratory Admin: Users in the Laboratory Admin role can perform all administrative tasks for their own lab, but cannot add, delete or update other labs, add users with the Institution Admin role, or set institution policy.
- **Epidemiologist**: People in the Epidemiologist role view test results in the Cepheid C360 data-visualization interface and can change their own passwords. Epidemiologists do not run patient tests and cannot access or change any of the Cepheid C360 administrative features.

Note Supranational institutions have slightly different user roles, as described later in this manual.

User Role Privileges

The following table summarizes the tasks that different user roles can perform on the system.

Task	Institution Admin	Laboratory Admin	Epidemiologist
Log in to Cepheid C360	Yes	Yes	Yes
View Medical Dashboard	Yes	Yes	Yes
Add, invite edit, disable users	Yes	Yes (own lab)	No
Edit own password and security questions	Yes	Yes	Yes
Restore own forgotten password	Yes	Yes	Yes
Add, delete labs	Yes	No	No
Edit labs	Yes	Yes (own)	No
Edit institution policy	Yes	No	No
View institution policy	Yes	Yes	No
View lab installation report	Yes	Yes (own)	No
View Cepheid C360 audit	Yes	Yes (own)	No

Task	Institution Admin	Laboratory Admin	Epidemiologist
Download C360 Sync client	Yes	Yes	No
Create, edit, delete data-collection policy	Yes	No	No
Create, edit, delete registration codes	Yes	No	No
View sharing requests	Yes	Yes	No
Accept, reject, stop sharing requests	Yes	No	No
Create, edit, delete notifications	Yes	Yes	Yes
View notifications	Yes	Yes	Yes

3.8.2 Adding Users

Follow these steps to add a new employee to your Cepheid C360 environment.

1. Under ADMIN click Users.

The **Users** screen opens.

- 2. Click **New User**, near the top right of the screen. The **New User** screen opens.
- 3. Under User Details, select a role for the user. Depending on the role selected, additional data-entry areas open in the New User screen.
- 4. Complete the additional fields as described below.
 - a) For a new person assigned the Laboratory Admin role, click the radio button for your institution under the Filter by institution name field under User Access. When you select the institution, the Laboratory Assignment box opens just to the right. Select the lab or labs for the new laboratory admin. Laboratory admins can be assigned to more than one lab in the list.

ser Details	User Access
ole - aboratory admin	 Filter by institution name Q Laboratory Assignment :
irst name + EPMedWest	Institution Location Supernation
ast name • tobileLabAdminThree	CEP Medical Multnomah CEP Med 1 Wes Portland CEP Med 1 Wes Portland
sername = estmobadmin3	4
	Comparison levels:
-mail nobadmin1@cepmedwest.com	District Subdistrict
ptional for Lab Assistant role	

Note

The displayed Comparison levels checkboxes vary with your selections.

b) For a new person assigned the Institution Admin role, select the institution in the **User Access** area, as above. An institution can have more than one person with

the Institution Admin role. Institution admins have admin rights for all labs and are not assigned to a specific lab.

c) For a new person assigned the Epidemiologist role, select the institution under User Access, as above. Then in the Access by pop-up menu that opens just to the right, select Everything, Location, or Laboratory. If you select Location, a new Locations entry field appears just below the pop-up menu. Enter a few letters to select from the list of locations associated with your institution. When you add an epidemiologist and select Location in the Access by pop-up, a Comparison levels setting appears beneath the institution name, with checkboxes for smaller divisions of the location that can include Country, Region, District and Subdistrict. The location divisions available vary by country and region. Note that epidemiologists do not need to be assigned to specific labs. However, if you select Laboratory in the Access by pop-up, the list of the institution's labs opens and the epidemiologist can be associated with one or more labs.

Note

Instead of the Epidemiologist role, supranational institutions have a Supranational Epidemiologist role. A person in that role can access data from more than one institution, depending on the institution's data-sharing arrangements. The **Access by** pop-up does not include Laboratory for the Supranational Epidemiologist role.

5. Complete the remaining fields, then click **Save** to accept the new record, **Save and** add another to continue adding employees, or **Cancel** to stop the process.

3.8.3 Adding Users In Batches

You can add up to 1500 users to Cepheid C360 in a single batch instead of one at a time. To do so, you must create a comma-separated list of the new users with all the items of information that will be uploaded to their **User Details** screens. There are three ways to do this: in a template you download from Cepheid C360, in a text file, or in Excel. Before starting, we recommend that you read the notes at the end of this topic.

Overview

1. Under ADMIN click Users.

The **Users** screen opens.

							+ New U	ser + Add Use
earch								d
aarch 🕕 li	nstitution 👻 Role		•					
Usemame	First Name	Last Name	Email 🛧	Phone Number	Institution	Laboratory	Role	Status
testadmingcphd.se	Frestadmin	Litestadmin			Cepheid		Lab assistant	+
solvatestadmin@cphd.se	F-soinatestadmin	L-soinatestadmin			Soina	SoinaLab13 more labs	Lab assistant	±
thach_lab_assistant1005	ThachFNLabAssistantfour	ThachLNLabAssistantfour			Thach institution 01	Thach Lab 01	Lab assistant	±
thach_lab_assistant0007	ThachFNLabAssistantseven	ThachLNLabAssistantseven			Thach institution 01	Thach Lab 01	Lab assistant	±
thach_lab_assistant_002	thach labassistant two	hoang			Thach institution 01	Thach Lab 011 more labs	Lab assistant	±
thach_assistant_003	thach assistant three	hoang			Thach institution 01	Thach Lab 01	Lab assistant	1
testadmin@cphd.cc	F-testadmin	L-testadmin			Cepheid		Lab assistant	±
soinatestuser@cphd.cc	F-soinatestuser	Lisoinatestuser			Soina	SoinaLab13 more labs	Lab assistant	±
usemame_500	bulkadminn	bulkik	abbigal_hane75@email.com		Soina	SolnaLab1	Laboratory admin	±
usemame_603	bulkadminn	bulkik	abdul.muphygemail.com		Solha	SoinaLab1	Laboratory admin	1

2. Click Add Users.

Cepheid C360 displays the **New Users CSV** screen. This is the screen for uploading user batch files. The **Instructions for Bulk user upload** and the **Guidelines for editing the sample CSV file** drop-downs provide details on the procedure and on how to format the upload file.

Note

elect users CSV file: Choose File No file chosen	L↓_ Download Sample CSV
stitution	~
Instructions for Bulk user upload	

Use the Template

To enter the user information into a template, click **Download Sample CSV**. This will download a file called *userexample.csv* to your computer. You can rename this file if you desire.

The *userexample.csv* file can be opened in a text editor such as Notepad or in Excel. For a small number of records it is easier to prepare the upload file in a text editor, as described later in this topic. Using a hybrid of Excel and Notepad for different stages of editing the *userexample.csv* file is more complex but allows you to enter numerous records in one step. This section describes the hybrid Excel/Notepad process.

- 1. Open the *userexample.csv* file in Excel.
- 2. Convert the field headings and sample data into columns by following these steps.
 - a. Click in the column A header to select the column.
 - **b.** Under the **Data** menu tab click **Text to Columns** to open the wizard.

1	A I	8	c	D	E	F	G	н
1	First Name	Last Name	Username	Phone Number	Email	Role	Laboratories	Password
2	labAdminFirstName	labAdminLastName	labAdminUsername	123456789	labAdminExample@email.com	laboratory_admin	exampleLaboratory1;ExampleLaboratory2;ExampleLaboratory3	
3	labAssistantFirstName	labAssistantLastName	labAssistantUsername	123456012		lab_assistant	exampleLaboratory1;ExampleLaboratory2;ExampleLaboratory3	ExamplePassword!
4	epidemiologistFirstName	epidemiologistLastName	epidemiologistUsername	123456789	epidemiologistExample@email.com	institution_epidemiologist		
5								

c. In step 1 of the **Text to Columns** wizard check that the **Delimited** radio button is selected, then click **Next**.

Convert Text to Columns Wizard - Step 1 of 3	?	×
The Text Wizard has determined that your data is Delimited.		
If this is correct, choose Next, or choose the data type that best describes your	data.	
Original data type		
Choose the file type that best describes your data:		
 Fixed width - Fields are aligned in columns with spaces between each 		
O Tixed wheth of the day are alighted in coldnins with spaces between each	in neru.	
Preview of selected data:	23456789 Usernam blogistU),: ne. Js: V
<		>
Cancel < Back <u>N</u> ext >	<u>F</u> in	ish

- **d.** In step 2 of the **Text to Columns** wizard, under **Delimiters** uncheck the **Tab** box and check the **Comma** box.
- e. Click Finish. Do not click Next.

Convert Text to Columns Wizard	- Step 2 of 3	?	Х
This screen lets you set the delimi in the preview below.	ters your data contains. You car	n see how your text is affe	cted
Delimiters	onsecutive delimiters as one ier: *		
First Name labAdminFirstName labAssistantFirstName epidemiologistFirstName	Last Name labAdminLastName labAssistantLastName epidemiologistLastName	Username labAdminUsername labAssistantUsernam epidemiologistUsern	< >
[Cancel < <u>B</u> ack	<u>N</u> ext > <u>F</u> inisł	ı

Data items in the rows are split into separate cells.

1	A	В	с	D	E	F	G	н
1	First Name	Last Name	Username	Phone Number	Email	Role	Laboratories	Password
2	User	01	01user		01user@medwest.com	laboratory_admin	CEP Med 1 West Stationary Lab	
3	User	02	02user		02user@medwest.com	lab_assistant	CEP Med 1 West Stationary Lab	
4	User	03	02user		02user@medwest.com	institution_epidemiologist	CEP Med 1 West Stationary Lab	
5								F .
6								
7	labAdminFirstName	labAdminLastName	labAdminUsername	123456789	labAdminExample@email.com	laboratory_admin	exampleLaboratory1;ExampleLaboratory2;ExampleLaboratory3	
8	labAssistantFirstName	labAssistantLastName	labAssistantUsername	123456012		lab_assistant	exampleLaboratory1;ExampleLaboratory2;ExampleLaboratory3	ExamplePassword!!
9	epidemiologistFirstName	epidemiologistLastName	epidemiologistUsername	123456789	epidemiologistExample@email.com	institution_epidemiologist		
10								

- 3. Import the rest of the user records you plan to upload to Cepheid C360. You can do this by copying and pasting or by using Excel's **Get Data** item on the **Data** menu tab. Depending on the source and format of the data you import, this step may require assistance from your institution's IT staff.
- 4. Save and close the CSV file.

Excel automatically converts the comma-delimited data to tab-delimited format. Because Cepheid C360 can import only comma-delimited data, you must perform a few extra steps to change the delimiter back to commas.

- 5. Open the CSV file in Notepad.
- 6. In Notepad you will notice that the individual data items are widely separated. This is because there are tabs between them instead of commas. Select the blank space containing a tab between any two items on the page and copy it to the Clipboard.
- 7. From Notepad's Edit menu select Replace....
- 8. In the **Replace** dialog paste the tab from the Clipboard into the **Find what:** field.

Note Notepad does not support using a special character, such as ^t, for a tab, and hitting the Tab key will simply move the cursor to the next item in the dialog.

9. Enter a comma in the **Replace with:** field.

Note

Replace	×
Find what:	Find Next
Replace with:	Replace
	Replace All
Match case	Cancel
Wrap around	

10. Click Replace All.

11. Save and close the file.

			-		\times
,Role,Laboratori	es,Pa	ssword			^
min,CEP Med 1 We	st St	ationary Lab,			
,CEP Med 1 West	Stati	onary Lab,			
pidemiologist,CE	P Med	1 West Statio	onary	y Lab	,
					>
Ln 1, Col 1	100%	Windows (CRLF)	UTF-1	16 LE	
1	min,CEP Med 1 We ,CEP Med 1 West pidemiologist,CE	min,CEP Med 1 West St ,CEP Med 1 West Stati pidemiologist,CEP Med		min,CEP Med 1 West Stationary Lab, ,CEP Med 1 West Stationary Lab, pidemiologist,CEP Med 1 West Stationary	min,CEP Med 1 West Stationary Lab, ,CEP Med 1 West Stationary Lab, pidemiologist,CEP Med 1 West Stationary Lab

The user records are now in comma-delimited format and the file is ready to upload to Cepheid C360, as described later in this topic.

Create a Text File

To enter information in a text file, create a separate row (a paragraph) for each person. Separate each item of information in the row with a comma. Include the following items in the order shown.

- First name
- Last name
- Username
- Phone number
- Email address
- Role
- Lab or labs
- Password

Use Excel

- 1. Create a new Excel file and save it in CSV format.
- 2. Use a separate row for each person.
- 3. Enter each data point in a separate cell.

The Excel upload file must be encoded as UTF-16LE. Excel supports UTF-16LE on Important the Macintosh but not on the Windows platform. Therefore, we do not recommend attempting to use Excel for the bulk upload process on a Windows system.

Upload the File

- 1. When the file is ready, select your institution from the **Institution** field.
- 2. Click Choose file.
- 3. Find the file in the dialog and click **Open**.
- 4. In the Add Users screen click Save.

The names and their associated details are added to the list of users.

Several error conditions can generate an error message when you attempt to upload the file. Examples include a lab name that doesn't match any lab at the institution and a username with too few characters.

New Users (CSV	
Select users Choose File	CSV file: a No file chosen	لل Download Sample CSV
Institution		
CSV	V file errors	^
Δ	username is either too short, too long or contains illegal chara Row: 3 – USER_VALIDATION_TOO_SHORT_TOO_LONG_OR_CONTAINS	

Notes

The first row in the userexample.csv file is the field names (First Name, Last Name and so on). Do not erase this row. If you create a text file include a paragraph at the top with the correct number of commas, or enter the field names. If you create an Excel file include a row Note of blank cells, or enter the field names. The bulk user import ignores content in the first row of the upload file, so if the row of field names is missing from the userexample.csv file, or the text or Excel file do not provide an extra row, the import process will skip the first name in the file. The userexample.csv file also includes several rows of example data. You can delete these Note rows to avoid including them in the upload. Roles must be entered exactly as shown below. We recommend that you copy and paste role names from the template file. Note laboratory admin • institution_epidemiologist Laboratories must be spelled exactly as they appear in your institution. We recommend that Note you copy and paste lab names from the list of labs in Cepheid C360. To add a new user to more than one lab, include multiple labs between the same set of Note commas, or in the same cell if you are using Excel, and separate the labs with semi-colons. If an item of information is not available, include an extra comma where that item belongs, or Note leave a blank cell if you are using Excel. All items are mandatory except a phone number. Note Enter phone numbers with a + sign and the country code.

3.8.4 Editing User Information

Follow these steps to modify information about an existing Cepheid C360 user.

- 1. Open the **Users** screen.
- In the Search area, enter a username, email address, or first or last name in the Search field. Select a role from the Role pop-up menu, and select whether you're searching for enabled or disabled employee accounts from the Status pop-up menu.

Note Hover over the information icon for a reminder of what criteria can be entered in the **Search** field.

Note	You can search and filter on more than one criterion.
NOLO	

The employees who meet the search criteria are listed in a table below the search area.

- **3.** Click the employee you're seeking. The **User Details** screen opens.
- 4. Click Edit.
- 5. In edit mode you can change all information on the **User Details** screen except the institution and location under the **User Access** area.

If a new user has received a Welcome email but has not logged in, admins will see aNoteResend Invitation button next to the Edit, Disable and Delete buttons. Click ResendInvitation to remind the new user to log in.

3.8.5 Suspending or Deleting User Accounts

To temporarily or permanently remove a user from Cepheid C360 follow these steps.

- 1. Open the **Users** screen and search for the user of interest.
- 2. In the table of users retrieved by the search, click the name of the user you're looking for to open that person's **User Details** screen.
- 3. To temporarily suspend the user's account, click **Disable**.
- Note Disable temporarily suspends the user's account, but the account remains in the system and can be reactivated when desired. To reactivate a disabled user, simply return to the User Details screen and click Enable



- 4. To permanently remove the user from the system, click **Delete**.
- **Note** Delete permanently removes the user from Cepheid C360. To reinstate a deleted user, you must recreate the account, following the same steps as for a new user.

3.9 Overview of Cepheid C360 Audit Trails

This section describes Cepheid C360 audit trails. It explains their purpose and how to use them.

Audit trails record detailed information about the actions each Cepheid C360 user performs. The audit trail interface provides a rich set of search and filter tools.

3.9.1 Searching and Filtering Audit Trails

Follow these steps to retrieve audit information from the database of recorded events.

- 1. Click Audit Trails in the left side menu under ADMIN.
- 2. In the Audit Trails screen, before beginning a search, click Clear filters. Any previous search criteria are removed.



3. In the Search pane, enter criteria for the records you want to retrieve.

Note

You can use any combination of the filters to narrow down the results.

Search					⊻
Institution	•	Entity Type	•	Search entity name or entity	id or client ip
Laboratory		Activity Type	•	Start date 2/7/2022	
User	•	Source Type	*	End date	

- a) Make selections as needed from the Laboratory and User pop-up menus.
- b) Select an audit type from the **Entity Type** pop-up menu. There are about 30 entity types to choose from, including assay, data-collection policy, registration code, sharing request, and test result.
- c) Select a value for the entity type from the Activity Type pop-up menu. Values available in the Activity Type menu depend on the entity type selection. For example, when Entity Type is set to Assay, the only item under Activity Type is Download CSV. When Entity Type is set to Data Collection Policy, the Activity Type choices are Create, Update, and Delete. And when Entity Type is set to Sharing Request, the Activity Type choices are Create, Update, Delete, Accept, and Reject. See the table below for details.
- **Note** There may be audit types that you don't recognize. Not all audit types apply to all instrument models.

Entity Type	Activity Types
Additional fields	Create, update, delete
Notification definition	Create, update, delete
Assay	Download CSV
Assay code sets	Create, update, delete
Assay group	Update

Entity Type	Activity Types
Audit	Download CSV
Bundle	Submit, publish, reject, disable, verify, download CSV
Bundle deployment rule	Create, update, delete, download CSV
Data collection policy	Create, update, delete
Document	Create, send document, delete
Institution	Create, update, delete, download CSV, update institution policy, create institution policy
Instrument	Create, update, delete, download CSV, refresh configuration item, view system configuration, view system files, view Sync event logs, view rejected updates, download file, force resend of test results, refresh policies, retrieve infinity logs, retrieve system logs, request file, view policies, force resync of policies, force resync of test results, accept, reject, approve
Laboratory	Create, update, delete, download CSV
Registration code	Create, update, delete
Sharing request	Create, update, delete, accept, reject
Tech collection project	Create, update, delete
Test result	Details viewed, visibility changed, Cepheid internal assay details viewed, Cepheid internal assay visibility changed, download test result archive file, download CSV, Cepheid internal assay download GXX
Test result log	Download CSV
Test results recurrent exports	Create, update, delete
User	Login, logout, logout inactive, logout session duration exceeded, login failure, adopted profile, authorization failure, password change, create, update, delete, enable, disable, forgot password, password reset, password reset by admin, download CSV, security question change, resend invitation
Self test data	Download CSV
Instrument log	Download CSV
l	

- d) Enter an additional criterion, if desired, in the **Search entity name or entity id or client ip** field. It is a free-text search field that can filter by instrument models, user names, telephone numbers, locations, or any other information captured in the audit database.
- e) Set start and end dates.
- 4. Click Search.

The records that meet the filter criteria are listed in a table below the **Search** pane. Sort the list by clicking any of the table's column headers, including the type of event, when it occurred, or the user involved.

3.9.2 Viewing Audit Trail Details

You can review details in an audit trail and export a batch of audit trails by following these steps.

1. Click an individual audit in the table to open it in the **Audit Details** screen. This screen has two panes, the **Audit trail details** pane and the **Audit trail changed attributes** pane.

Information on the **Audit trail details** pane varies slightly with the type of audit. Most include the event type, the person involved, a time stamp, and similar basic information.

Audit trail details	
Timestamp :	Mar 7, 2022, 10:06:35 AM
Entity Type :	User
Activity Type :	Disable
Entity Name :	CEPMedWest EpidemiologistTwo
Entity Id :	westepid2
User :	westadmin1
Access Role :	Institution admin
User's Institution GUID :	7cfb7a5a-4969-4bac-b40e-76b3770ee94d
Institution :	CEP Medical Center 1 West
Institution GUID :	7cfb7a5a-4969-4bac-b40e-76b3770ee94d
Client IP :	100.21.142.78
Source :	C360

2. Scroll down to the bottom of the Audit Details screen to view the Audit trail changed attributes pane. This provides specific details about the audit you are reviewing. For example, for a data-collection policy audit item, the Audit trail changed attributes shows the old rule and the new rule, while for a login failure it shows what occurred to prevent the person from logging in.

Attribute	Previous Value	New Value	
Name	CEP Medical Center 1	CEP Medical Center 1 West	

- **Note** Not all audit types involve changed attributes. For those audit types the **Audit trail changed attributes** pane does not appear.
 - 3. Click the **Download CSV** icon to export the filtered and sorted list to a CSV file.
- **Note** The **Audit Trails** CSV file includes only the information in the table. Information from the **Audit Details** screens is not included.

4 Supranational Institutions and Data-Sharing

This chapter describes how supranational institutions set up and send data-sharing requests, and how nonsupranational institutions manage the requests.

An institution defined as supranational in Cepheid C360 is an institution that aggregates medical test data from other medical centers. It may be part of a public-health agency such as the CDC or the WHO, or an entity of a private medical network tasked with gathering and interpreting information from the network's other institutions. Supranational institutions do not operate their own labs. Instead, their administrators request data from other institutions, and their epidemiologists interpret the data.

Note An institution is defined as supranational when Cepheid creates it in Cepheid C360. Once an institution has been defined as supranational it cannot be converted to a regular institution.

An institution can be enrolled in Cepheid C360 twice, as a supranational institution and a nonsupranational institution. That would allow it to issue sharing requests and to accept sharing requests from other institutions. To configure two versions of an institution, provide different identifiers and slightly different names. Keep in mind that supranational institutions cannot have laboratories.

To gather medical test data, a supranational institution sends out sharing requests that specify what information it is seeking. A sharing request might specify, for example, the results of a set of assays for a particular date range. The receiving institution or institutions can accept or reject the request. However, only supranational institutions and Cepheid Technical Support can initiate data-sharing requests.

The Supranational Admin and Supranational Epidemiologist roles have slightly different privileges in Cepheid C360 than the Institution Admin and Epidemiologist roles have. Generally, the supranational roles do not provide access to features that are internal to an institution, such as adding and inviting new institution personnel, adding and editing labs, viewing instrument configurations, and setting institution policy. In the same way, supranational admins and epidemiologists have a few privileges that institution personnel do not, such as adding and inviting new supranational personnel, and issuing or modifying sharing requests.

Data collected with data-sharing requests becomes available to the Cepheid C360 datavisualization tools. However, the shared data provided to the supranational institution includes only the test results collected by the sharing institution. Lab information, personnel, and other information is not included.

Note A supranational institution cannot distribute data gathered with sharing requests to other institutions.

4.1 Making a Request To Share Data

Administrators and epidemiologists at supranational institutions can follow these steps to generate sharing requests. Administrators and epidemiologists at nonsupranational institutions do not generate sharing requests, but they should understand how sharing requests work.

Note

Note

For a nonsupranational institution to participate in sharing data, it must be configured to accept sharing requests at the time the institution is created in Cepheid C360. An institution configured to accept data-sharing requests is visible to supranational institutions that may send sharing requests. The institution is not obligated to accept them; it can accept or reject individual sharing requests. An institution not configured to accept data-sharing requests

- individual sharing requests. An institution not configured to accept data-sharing requests does not appear in the list of potential sharing institutions that supranational institutions draw from.
 - 1. Under ADMIN, click the arrow next to the **Configurations** item to expand it. Then click **Sharing Requests**.

The list of previously created sharing requests opens in a table. The table can be sorted by institution, or alphabetically by each request's name.

Name	Institution	Assays	Periodicity	Data category	Granularity	Data from
BCR 2020s overview	CEP Supranational Medical East	Xpert BCR-ABL Monitor, Xpert BCR-ABL Ultra, Xpert BCR-ABL Ultra p190	Monthly	None	Laboratory	1/1/20
C.Diff Metro Portland	CEP Supranational Medical East	Xpert C. difficile	Daily	None	Test Result with Patient Demographics	1/1/22
Carba-R West	CEP Supranational Medical East	Xpert Carba-R	Real time	None	Laboratory	1/1/21
Fil and FV urban areas	CEP Supranational Medical East	Xpert FII & FV	Daily	None	Country	1/31/21
GBS south	CEP Supranational Medical East	Xpert GBS LB, Xpert GBS	Real time	None	Test Result with Patient Demographics	2/14/22
Hemo fever	CEP Supranational Medical East	Xpert Ebola	Daily	None	Laboratory	1/31/22
Multnomah schools	CEP Supranational Medical East	Xpert Norovirus	Daily	None	Test Result with Patient Demographics	1/1/21
Recent STD incidence	CEP Supranational Medical East	Xpert HPV 16_18-45, Xpert HPV HR, Xpert HIV Qual, Xpert HIV Quant	Daily	None	Subdistrict	1/1/22
Recent Throat and Lung	CEP Supranational Medical East	Xpert Flu/RSV XC (Flu only), Xpert Flu, Xpert MRSA/SA Nasal Complete, Xpert MRSA, Xpert Xpress SARS-CoV-2/Flu/RSV, Xpert Xpress Strep A	Daily	None	Test Result with Patient Demographics	1/31/22
		Items	per page: 25	▼ 1-9	9 of 9 < <	> >

2. Click Create new sharing request. The New sharing request screen opens.

Note

Note

Only Supranational Institution Admin users can create a sharing request.

< Sharing Requests / New sharing request	CEPSupra InstAdminOne Supernational admin
Properties	
Name * Recent Throat and Lung	
Request data since • 1/31/2022	Ē
Assays * Xpert Flu/RSV XC (Flu only) ③ Xpert Flu ③ Xpert MRSA/SA Nasal Complete ③ Xpert MRSA ③	
Xpert Xpress SARS-CoV-2/Flu/RSV 🛞 Xpert Xpress Strep A 🛞	Select none
Assays that currently belong to other sharing request will not be available for selection.	
Applies to *	
Locations Institutions Add institutions	
Search: CEP Medical Center 1 West, CEP Medical Center 2 South 	▼
Data aggregation options	
Granularity: O Country O Region O District O Subdistrict O Laboratory O Test result 💿 Test	result with patient demographics
Time aggregation: 🔿 Real time 💿 Daily 🔿 Weekly 🔿 Monthly	
Get data 1 e days after the end of each day	

- 3. Fill out the fields in the **Properties** pane.
 - a) Enter a recognizable name for the sharing request in the **Name** field, such as Influenza incidence in metropolitan New York.
 - b) Click the calendar icon next to the **Request data since** field and select a start date.

If the start date is in the past, the sharing request retrieves the data retroactively.

c) Either click in the **Assays** field and select the tests of interest from the menu of choices, or click **Select all** in the menu.

If you select an assay by mistake, click the small "X" to its right to remove it from the request.

You can send more than one sharing request to the same institution and you can include more than one assay in a request, but each assay can only be included in Important one request. To retrieve test results for a particular assay from multiple sharing institutions, include them all on the request. We recommend that you plan sharing requests carefully to avoid duplication.

- 4. In the **Applies to** pane select either the **Locations** or the **Institutions** radio button.
 - a) Click in the Search field. A menu of locations or institutions opens, depending on which radio button you selected.
 - b) Click the checkboxes of the locations or institutions you want to add to the sharing request. You can select multiple locations or institutions. There is no limit to the number of institutions included in a request. If you select by location, only the institutions in that location and that are configured to accept sharing requests receive the request.

Note If some of the institutions in a sharing request decline the request, data will still be retrieved from those institutions that accept the request.

- 5. Set the following details in the Data aggregation options pane.
 - a) Choose one radio button for **Granularity**. The choices are as follows:
 - Country
 - Region
 - District
 - Subdistrict
 - Laboratory
 - Test result
 - Test result with patient demographics

Note If an institution does not collect patient demographics or is set up to prevent sharing that information, it will not be included in the data shared after the request is accepted even if the requesting institution includes that in the sharing request.

Not all geographical areas provide the same levels of granularity. For details about your location contact Cepheid Technical Support.

- b) Choose one radio button for **Time aggregation**. The choices are as follows:
 - Real time
 - Daily
 - Weekly
 - Monthly
- c) The choices for the final setting, Get data "X" days after..., vary depending on the Time aggregation setting. For example, if you select the Weekly radio button and enter 2 in the Get data "X" days after... field, data from institutions that accept the sharing request will be retrieved two days after the end of each week. These settings are visible when the institution admin at the sharing institution reviews the request on the Sharing Request Details screen.
- 6. Click Save.

The sharing request is added to the table of requests at the supranational institution and at the institution or institutions receiving the request. However, it will not be active until the specified institution or institutions accept the request.

Note After a sharing request has been created, a new pane, **Requested acceptance status**, appears at the bottom of the screen. Click the arrow next to the title to see whether the listed institutions have accepted the request.

SathiyaInstitution		
Xpert Xpress SARS-CoV-2/Flu/RSV	PENDING	
Xpert Xpress SARS-CoV-2/Flu/RSV	PENDING	
STG Institution		
Xpert Xpress SARS-CoV-2/Flu/RSV	PENDING	
Xpert Xpress SARS-CoV-2/Flu/RSV	PENDING	
Thach Institution 01		
Xpert Xpress SARS-CoV-2/Flu/RSV	PENDING	
Xpert Xpress SARS-CoV-2/Flu/RSV	PENDING	

4.2 Modifying a Sharing Request

After a request has been created, some of the parameters can be changed and some cannot. To change a request, open it by simply clicking it in the table of sharing requests.

The following parameters can be changed:

- The request's name
- The assays requested
- Institutions or locations can be added but not removed.

The following parameters cannot be changed:

- The start date
- Any of the data-aggregation options

```
Note
```

After a sharing request has been configured to apply to institutions or to locations in the **Applies to** pane, that setting cannot be changed.

4.3 Delete a Sharing Request

A supranational institution can delete a sharing request it has created whether or not the receiving institutions have accepted the request. Follow these steps to delete a request.

1. Open the request by clicking it in the table of sharing requests. The sharing request's window opens.

Note Only people with the Supranational Institution Admin role can delete a sharing request.

- 2. Click **Delete** just above the right side of the **Properties** pane.
- **3.** When the confirmation dialog opens click **Yes**. The sharing request is deactivated and removed from the table of requests. Any data received from the sharing institution is removed from the requesting institution's aggregated data. (Deleting a sharing request does not remove data from the sending institution's database.) The request also is removed from the table of requests at the sharing institution. This occurs whether or not the institution has accepted the request.

4.4 Responding to Sharing Requests

Institutions that receive sharing requests can follow these steps to address the requests.

1. Under ADMIN, click the arrow next to the **Configurations** item to expand it. Then click **Sharing Requests**.

The list of pending and accepted sharing requests for your institution opens in a table. The table can be sorted by status, alphabetically by each request's name, or by the institution making the request.

Status	Name	Institution	Assays	Periodicity	Data category	Granularity	Data from
PENDING	BCR 2020s overview	CEP Supranational Medical East	Xpert BCR-ABL Monitor, Xpert BCR-ABL Ultra, Xpert BCR-ABL Ultra p190	Monthly	None	Laboratory	1/1/20
PENDING	C.Diff Metro Portland	CEP Supranational Medical East	Xpert C. difficile	Daily	None	Test Result with Patient Demographics	1/1/22
PENDING	Carba-R West	CEP Supranational Medical East	Xpert Carba-R	Real time	None	Laboratory	1/1/21
ACCEPTED	Multnomah schools	CEP Supranational Medical East	Xpert Norovirus	Daily	None	Test Result with Patient Demographics	1/1/21
ACCEPTED	Recent STD incidence	CEP Supranational Medical East	Xpert HPV 16_18-45, Xpert HPV HR, Xpert HIV Qual, Xpert HIV Quant	Daily	None	Subdistrict	1/1/22
PENDING	Recent Throat and Lung	CEP Supranational Medical East	Xpert Flu/RSV XC (Flu only), Xpert Flu, Xpert MRSA/SA Nasal Complete, Xpert MRSA, Xpert Xpress SARS-CoV- 2/Flu/RSV, Xpert Xpress Strep A	Daily	None	Test Result with Patient Demographics	1/31/22
			Items pe	er page: 25	▼ 1-60	f6 < <	> >

2. Click a request in the table to open it. Review what details the requesting supranational institution has asked for.

Properties				
Requested by	CEP Supranational Medical East			
Requested data since	1/1/21, 4:00 PM			
Involved assays	Xpert Norovirus			
Requested data aggregation options				
Granularity	Test Result with Patient Demographics			
Time aggregation	Daily			
Delay	1 days			
Pending requests				
Assays	Xpert Norovirus			
Status	PENDING			
Share request data consent				
User CEPSupra InstAdminOne of Institution CEP Supranational Medical East has created a sharing request to view data from your organization. The granularity of this sharing request is Test Result with Patient Demographics, meaning Test Result with Patient Demographics explanation. Please accept or reject the request.				
✓ Agree to share this requested data	Reject sharing this requested data			

3. At the bottom of the sharing request screen is a box called **Share request data** consent. Click either **Agree to share this requested data** or **Reject sharing** this requested data.

Important The institution that receives a sharing request is responsible for complying with applicable privacy and data-protection laws.

4.5 Stopping Data Sharing

An institution that has accepted a sharing request can follow these steps to stop sharing data.

1. Open the request by clicking it in the table of sharing requests.

The sharing request's window opens.

2. In the Data being shared pane at the bottom of the screen click Stop sharing.

Assays	Xpert Norovirus
Status	ACCEPTED
Stop sharing	

Cepheid C360 stops sending new data to the requesting institution. Data previously shared with the requesting institution is no longer visible to the supranational institution. Stopped sharing requests remain in the list of requests.

4.6 Restarting Stopped Data Sharing

After having stopped a sharing request, you can follow these steps to start sharing data again.

1. Open the request by clicking it in the table of sharing requests.

The sharing request's window opens. The **Stop sharing** button in the **Data being shared** pane now reads **Start sharing this data**.

2. Click Start sharing this data.

Cepheid C360 begins sending the requested data to the supranational institution that initiated the request. If the request's start date was before or during the period the sharing request was stopped, any missed data is retrieved retroactively.