CONFIRM ADMINISTRATOR



micromeritics®

GUIDE

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1 OVERVIEW

The Micromeritics Confirm application enables laboratory managers in 21CFR11 environments to develop analysis methods, enforce industry standards, produce audit trails, and enables laboratory analysts to perform analyses and produce reports.

When the Confirm application is installed, one Confirm application controller and two Confirm groups are created in Windows Users and Groups. Refer to <u>User Permissions on the next</u> <u>page</u> for specific default rights of members assigned to each Confirm group.

Application User default name: mic_[analyzer model number]_controller

Developer Group default name mic_[analyzer model number]_developer

Analyst Group default name mic_[analyzer model number]_ analyst

Once an account holder logs in and launches the Confirm application, it is launched using the application controller's permissions. Analysts and developers must not be allowed access to this account. After installation, use Windows Users and Groups to create and maintain users. See *Maintaining Confirm Users and Groups on page 16*.

Prior to installing the Confirm application, the following prerequisites must be met:

- The Confirm application installer must have Windows Administrator rights.
- Computer must have an operating system of Windows 10 Professional or Windows 10 Enterprise or higher.
- Configure an Ethernet port on the computer to communicate with the analyzer. The IP address must be 192.168.77.100. Refer to the computer operator manual for instructions on changing the IP address.



USER PERMISSIONS

The Confirm application uses Windows Users and Groups to control access to the Micromeritics Confirm application. When the Micromeritics Confirm application is installed, two Confirm groups are created. Confirm users must be assigned to only one group.

Confirm User Name	Description
mic_[analyzer model number]_controller	mic_[analyzer model number]_controller is the user name used by all installations.
	■ This user should have complete control over the installation directory.
	■ The application is launched under this user name and has this user's privileges to the windows file system.
	■ This user should not be used by anyone or any other software that is not a Micromeritics application.
	■ The system administrator has the option of modifying this account so that the password never expires. Alternatively, if the password does expire while the application is running, the application automatically changes the password for this account.



Confirm Group Name	Description
Developer Group	The default Developer group name is mic_[analyzer model number]_developer. Members of the Developer group:
	 have rights to all functions of the Micromeritics application - including Advanced option presentation which allows the creation and modification of methods, sample files, and parameter files. can run an analysis. can also be assigned Administrator rights which control the user
	profiles.
Analyst Group	The default Analyst group name is mic_[analyzer model number]_analyst. Members of the Analyst group:
	 have access to the <i>Basic</i> presentation option only. may create sample files from pre-defined methods and can modify only a limited number of input fields.



User Permissions within the Application

Function	Developer	Analyst
Create methods	✓	
Create or modify sample files and parameter files	✓	
Create or modify sample files and parameter files only from the available method and parameter file		√
Run analyses	✓	✓
Generate reports	✓	✓
List and print sample files	✓	✓
Perform routine maintenance	✓	✓
Enable manual control	✓	✓
Change limited analysis conditions prior to performing an analysis	✓	✓
Change report options after analysis	✓	✓
Access to the Advanced option presentation	✓	
Access to the Basic option presentation	✓	✓
Access to directories outside of the installation directory and data directory	√*	√ *
Can overwrite, rename, or delete existing files in the data directory	√ *	√ *
Can perform diagnostics	✓	✓
Can perform calibration	✓	
Can view and print the system audit trail	✓	✓
Can manage libraries	✓	✓
Can change system units and gas selections	✓	✓
Can add log entries	✓	✓

^{*} With administrative privileges only.



2 SOFTWARE INSTALLATION IN 21CFR11 ENVIRONMENTS

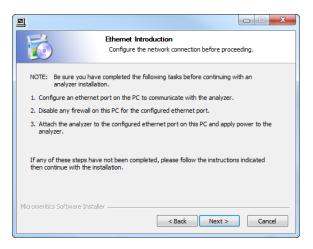
The following Confirm application prerequisites must be met prior to installing the software:

- Windows 10 Professional or Windows 10 Enterprise (or higher) must be installed.
- Configure an Ethernet port on the computer to communicate with the analyzer. The IP address must be 192.168.77.100. Refer to the computer operator manual for instructions on changing the IP address.
- Attach the analyzer to the Ethernet port on the computer. Use an Ethernet switch if multiple analyzers or Smart VacPreps will be attached.
 - 1. Insert the installation media into the computer. The setup program automatically starts. If the setup program does not immediately start, navigate to the media device, then locate and double click the *setup.exe* file.
 - 2. Click Next on the Welcome window.

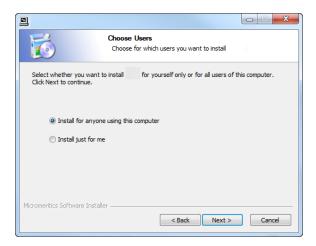


- 3. On the Ethernet Introduction window, verify that all prerequisites have been met.
 - a. If not, click **Cancel** and complete the steps, then restart the installation program. Do not proceed with installation until these tasks have been completed.
 - b. If the prerequisites have been met, click Next.



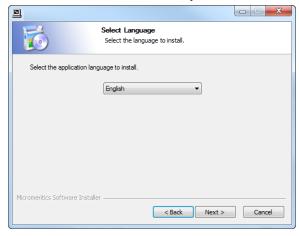


- 4. On the Choose Users window, select either of the following, then click Next:
 - Install for anyone using this computer. Anyone who logs on to this computer will have access to the analyzer program. This is the recommended selection.
 - **Install just for me**. Only the person logged on to the computer at the time of installation will have access to the analyzer program.





5. On the *Select Language* window, select the default language of the program, then click **Next**. This window may not be available in all installations.



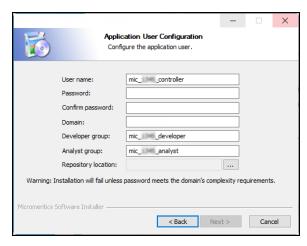
6. On the Choose Install Location window, verify that sufficient disk space is available to continue the installation. If not, click Cancel and free up the minimum required disk space. If the disk space is OK, click Next to accept the default installation directory, or click Browse to change the installation location, then click Next.





7. The Application User Configuration window is used to create the application controller and the two groups used by the Micromeritics Confirm application. Use the <u>Users and Groups</u> <u>Worksheet for 21CFR11 on page 21</u> to determine group members. This worksheet may have been completed in the <u>Pre-installation Instructions and Checklist</u> document. When the form is complete, click <u>Next</u>.

It is recommended to use the default values for this step.

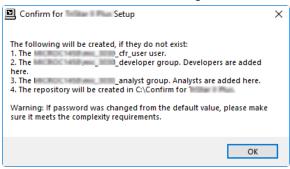


Field	Description	
User name	Enter the user name for the Micromeritics Confirm application conroller. If this name does not already exist, it will be added to the Windows Users group. The default user name is mic_[analyzer model number]_controller.	
Password	Enter the password for the application controller. Ensure the password meets the complexity requirements. The application controller password must remain in sync with the mic_[analyzer model number]_controller in Windows Users and Groups. If not, a messages displays. Place of the Application User. Enter new credentials? No Click Yes to display a prompt to change the password.	
Confirm Password	Re-enter the password for the application controller.	
Domain	Enter the domain name for this user. If the computer is not on a network, enter the computer name.	

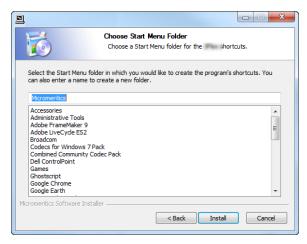


Field	Description
Developer group	It is recommended to use the default entry for the Developer group. The default entry ensures a unique name will be created in Windows Users and Groups.
Analyst group	It is recommended to use the default entry for the Analyst group. The default entry ensures a unique name will be created in Windows Users and Groups.
Repository location	When selecting a different repository location for analysis files, ensure that no specific user owns the directory other than the application controller otherwise read/write issues will occur. This repository directory must also be empty.

8. A pop-up window confirms the changes made for groups, users, and the repository location. Confirm that these changes are correct. Click OK.

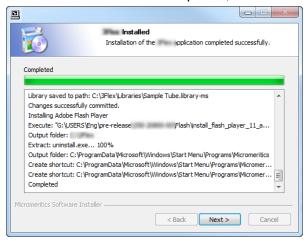


- 9. On the Choose Start Menu Folder window, select a folder for the program shortcut:
 - click Install to accept the default location, or
 - select another folder from the list, then click Install, or
 - enter a new folder name in the text box, then click install

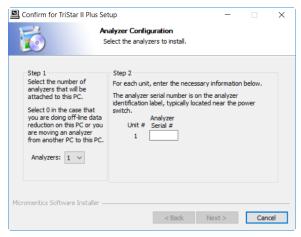




10. When installation completes, the *Installed* window displays. Click **Next**.



11. The *Analyzer Configuration* window is used to configure the system for each analyzer and serial number to be installed.



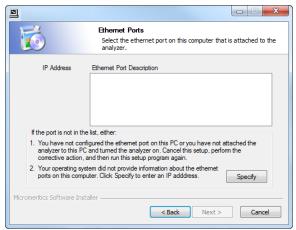
a. In the Step 1 group box:

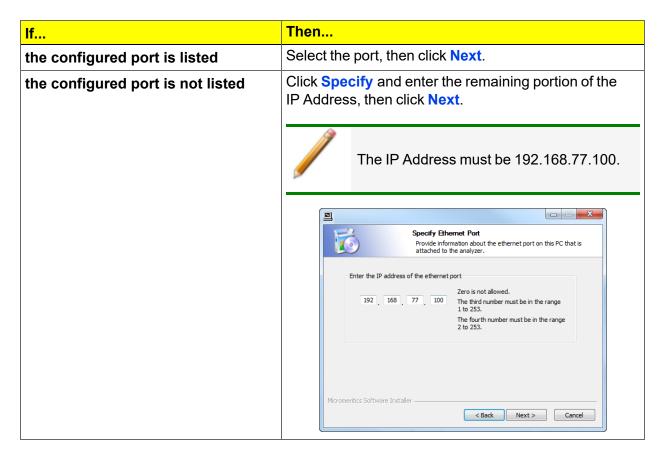
If	Then
installing the analysis program during initial installation	select the number of analyzers to be installed.
using the analysis program for off- line data reduction	select 0.
moving an analyzer from another computer to this computer	select 0.

- b. In the *Step 2* group box, enter the serial number for each analyzer to be attached to this computer. The serial number label is located either near the incoming power supply or near the **ON/OFF** switch.
- c. Click Next.



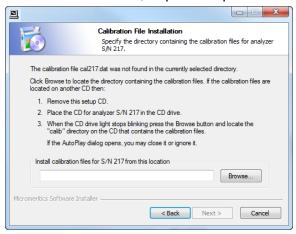
12. On the *Ethernet Ports* window, select one option from the following table:







- 13. If prompted for calibration files, insert the calibration media that shipped with the analyzer.
- 14. Click **Browse** to locate and select the *[calibration]* directory. Click **Next**. If not prompted for calibration files, skip this step.

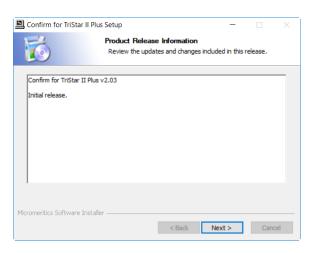


15. On the *Analyzer S/N [n] Installed* window, click **Next**. A window displays for each unit installed.

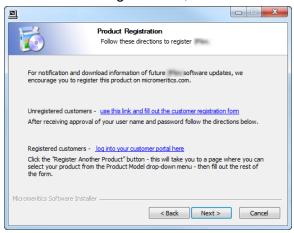


16. The *Product Release Information* window contains information about updates and changes included in the release. Click **Next**.





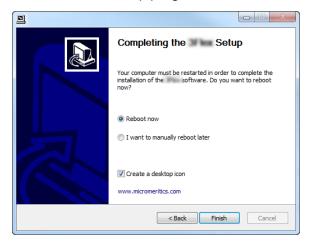
- 17. The *Product Registration* window is available to register the analyzer and to receive future notifications of software updates.
 - Click the appropriate link to register the product or to log in to the customer portal.
 After registration, click Next.
 - b. To register later, click Next.





- 18. On the Completing the Setup window, select either:
 - Reboot now
 - I want to manually reboot later

To create a desktop shortcut, select the *Create a desktop icon* checkbox. Click **Finish** to close the setup program.



In Windows Users and Groups, the Application Controller must be added to one of the Confirm groups before the Application Controller can run the Confirm program. See <u>Maintaining Confirm Users and Groups on page 16</u>.



Uninstall Software in 21CFR11 Environments

When the software is uninstalled using *uninstall.exe*, only the files required to run the application are removed. Parameter files, sample files, reports, calibration files, and data files are not removed.

To uninstall the software, double-click the *uninstall.exe* file located in the software installation directory, then follow the prompts.

CFR Note

To uninstall the Micromeritics Confirm application, the owner of the application directory and its contents must be set to the account of the administrator that is removing the application installation. This account must also have permission to modify the application directory and its contents. This may require modification to the owner and to the access permissions of the application directory and its contents.

Upon uninstalling the Confirm application, the system administrator should go into Windows Users and Groups to remove the Confirm users and groups. See the Confirm Administrator Guide [part number 004-42821-01].

Depending on the network, Windows may not allow the uninstall.exe program to run. If this happens. follow these steps:

- 1. In Windows Users and Groups, verify that the current user is not a member of the analyst group or developer group. If so, remove the user from the group(s). Log OFF, then log back ON to the computer.
- 2. In Windows Explorer, in the Confirm installation directory, double-click the *uninstall.exe* file to run the uninstall program.

SOFTWARE UPDATES



A User Account Control in the Windows operating system must be enabled to ensure all components of the Micromeritics application are correctly installed. If UAC is not enabled, right-click the *setup.exe* installer file and select *Run as administrator*.

The most current version of the instrument software can be found on the Micromeritics web page (www.Micromeritics.com).

When performing a software update, existing data files are not overwritten.

Insert the setup media into the media drive. The setup program starts automatically. If the program does not start automatically, navigate to the installation media drive, locate and double-click the *setup.exe* file.



3 MAINTAINING CONFIRM USERS AND GROUPS

ACCESS COMPUTER MANAGEMENT



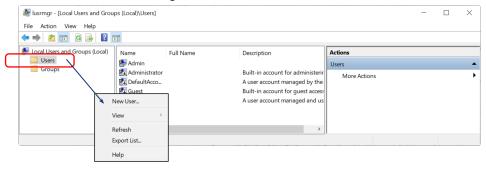
As updates are made to the Windows operating system, the following images and steps may change. If necessary, consult the internet for updates.

- 1. Hold down the **Windows** key while pressing **R** to open the *Run* box.
- 2. In the *Run* box, enter *lusrmgr.msc*. Press **Enter** or click **OK**. The Users and Groups window displays.

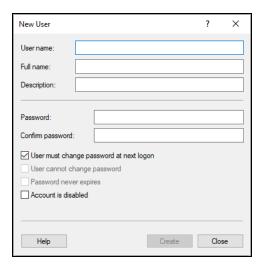


CREATE USER ACCOUNTS

- 1. Open the *Users and Groups* window.
- 2. In the first column, right-click the *Users* folder and select *New User*.







3. Use the following table to create the new user: **New User Profile**

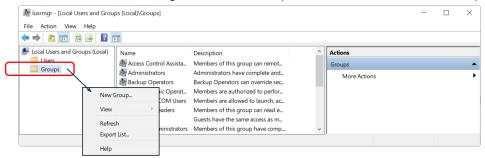
Field or Option	Description
User name	Enter the login name to be used for the Confirm application. This entry displays in the <i>Name</i> column.
Full name	Enter the full name of the user. This entry displays in the <i>Full Name</i> column.
Description	(Optional.) Enter a description for the user. This entry displays in the <i>Description</i> column.
Password	Enter a password for the user.
Confirm password	Enter the password again to confirm the previous entry. The password must meet the minimum requirements policy set by your company.
User must change password at next login	Select to force the user to change the default password upon initial login to the computer.
User cannot change password	Option is disabled if <i>User must change password at next logon</i> is checked. If selected, the user cannot change their own password.
Password never expires	Option is disabled if <i>User must change password at next logon</i> is checked. If selected, the password will not have an expiration period.
Account is disabled	Select to disable the user account.

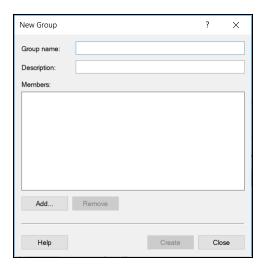
4. Click **Create**. Enter another user or click **Close** to close the window. Users may not display until the window is closed.



CREATE USER GROUPS

- 1. Open the Users and Groups window.
- 2. In the first column, right-click the Groups folder and select New Group.





3. Use the following table to create the new user:

New Group Profile

Field or Option	Description
Group name	Enter a descriptive name of the User Group.
Description	Enter a description for the user. This entry displays in the <i>Description</i> column.
Members	Displays a list of members in an existing group. See also <u>Assign a</u> <u>User to a Group on the facing page</u> .

4. Click **Create**. Enter another user or click **Close** to close the window. Users may not display until the window is closed.



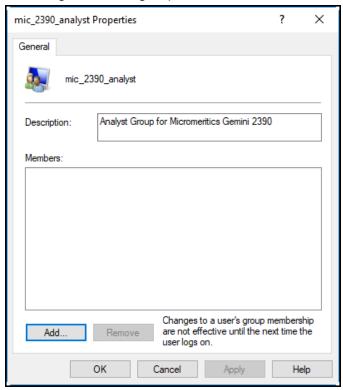
ASSIGN A USER TO A GROUP

Upon installation of the Micromeritics Confirm application, the Analyst and Developer groups are created. Group names should not be changed, however, descriptions may be modified. See <u>User</u> <u>Permissions on page 2</u> for a list of group permissions.

The group names assigned by the Confirm installation process use the following naming convention:

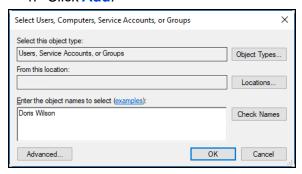
mic_[analyzer model number]_analyst mic_[analyzer model number]_developer

- 1. Open the *Users and Groups* window.
- 2. Select Groups in the first column to display a list of all groups.
- 3. Right-click the group name in the second column and select Add to Group.





4. Click Add.



- 5. Verify that *From this location* points to the correct location. If not, click **Locations** to change. This location may be either a network domain or the local computer name.
- 6. In the *Enter the object names to select* box, enter the name of the user to add to this group. If necessary, change the *Locations* field to where the user name is stored. Click **OK**. The user name is added to the list of users for the selected group. Continue this process until all applicable users have been added to the group.
- 7. Click Apply, then click OK.
- 8. Repeat this process until all applicable users have been added to each group.



USERS AND GROUPS WORKSHEET FOR 21CFR11

Micromeritics	Confirm application:	Developer	Analyst
User Name Full Name			
User Name Full Name			
User Name			
User Name Full Name			
User Name Full Name			
User Name Full Name			
User Name Full Name			
User Name Full Name			
User Name Full Name			