CONFIRM ADMINISTRATOR



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004-42821-01 Nov 2024 (Rev D)

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PATENTS

For patent information, visit <u>www.Micromeritics.com/patents</u>.

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Table of Contents

1 Overview	_ 1
User Permissions	2
2 Software Installation in 21CFR11 Environments	_ 5
Uninstall Software in 21CFR11 Environments	15
Software Updates	15
3 Maintaining Confirm Users and Groups	.16
Access Computer Management	16
Create User Accounts	16
Create User Groups	18
Assign a User to a Group	19
Users and Groups Worksheet for 21CFR11	.21

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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_[<i>analyzer model</i> <i>number</i>]_controller	mic_[<i>analyzer model number</i>]_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 auto- matically changes the password for this account. 	

Confirm Group Name	Description
Developer Group	The default Developer group name is <i>mic_[analyzer model number]_developer</i> . 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 <i>mic_[analyzer model number]_analyst</i>. 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 avail- able 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	✓	 ✓
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.

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- 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.

Choose Users Choose for which users you want to install	
Select whether you want to instal for yourself only or for all users of t Click Next to continue.	this computer.
Install for anyone using this computer	
🔘 Install just for me	
Micromeritics Software Installer	Cancel

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	Select Language Select the language to install.
Select the application lang	guage to install.
	English 👻
Micromeritics Software Installe	
micromenucs portware Installe	< Back Next > Cancel

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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**.

6	Choose Install Location Choose the folder in which to install the software.			
Setup will install in the following folder. To install in a different folder, dick Browse and select another folder. Click Next to continue.				
Destination Folder				
	Browse			
Space required: 666.6M Space available: 50.8G				
Micromeritics Software Ins				
	< Back Next > Cancel			

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- 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 Pre-installation Instructions and Checklist document. When the form is complete, click Next.

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

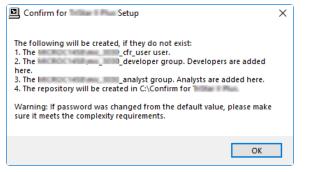
Continue	or Accorpc II 1345 Sets		-		×
6	Application User Configuration Configure the application user.				
	User name: Password: Confirm password: Domain: Developer group: Analyst group: Repository location:	miccontroller			
Warning: Installation will fail unless password meets the domain's complexity requirements.					
Micromeritics S	ioftware Installer ———	< Back N	lext >	Can	cel

Field	Description	
User name	Enter the user name for the Micromeritics Confirm application con- troller. If this name does not already exist, it will be added to the Win- dows Users group. The default user name is <i>mic_[analyzer model</i> <i>number]_controller</i> .	
Password	Further for the password for the application controller. Ensure the password meets the complexity requirements. Image: 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. Image: 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. Image: The application control of the application user. Enter new credentials? Image: The application user. Enter new credentials?	
	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 net- work, enter the computer name.	

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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.

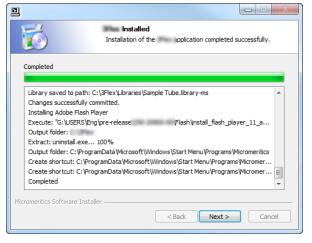


- 9. On the Choose Start Menu Folder window, select a folder for the program shortcut:
 - click Install to accept the default location, or
 - select another folder from the list, then click Install, or
 - enter a new folder name in the text box, then click Install

	hoose Start Menu Folder Choose a Start Menu folder for the hortcuts.
Select the Start Menu folder in can also enter a name to creat	which you would like to create the program's shortcuts. You te a new folder.
Accessories Administrative Tools Adobe FrameMaker 9 Adobe LiveCyde ES2 Broadcom Codecs for Windows 7 Pack. Combined Community Codec I Dell ControlPoint Games Ghostscript Google Chrome Google Earth	Padk
Micromeritics Software Installer –	< Back Install Cancel



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.

Confirm for TriStar II Plus Se	etup	-		\times
	nalyzer Configuration Select the analyzers to install.			
Step 1 Select the number of analyzers that will be attached to this PC. Select 0 in the case that you are doing off-line data reduction on this PC or you are moving an analyzer from another PC to this PC. Analyzers: 1	Step 2 For each unit, enter the necessary i The analyzer serial number is on the identification label, typically located switch. Analyzer Unit # Serial # 1	analyzer		
Micromeritics Software Installer –	< Back N	ext >	Can	cel

a. In the *Step 1* group box:

lf	Then
installing the analysis program dur- ing 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:



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If	Then
the configured port is listed	Select the port, then click Next.
the configured port is not listed	Click Specify and enter the remaining portion of the IP Address, then click Next .
	The IP Address must be 192.168.77.100.
	Specify Ethemet Pot Provide information about the ethernet port on this PC that is attached to the analyzer. Enter the IP address of the ethernet port Ig2 168 77 100 Zero is not allowed. The third number must be in the range 1 to 253. The fourth number must be in the range 2 to 253.
	Micromeritics Software Installer < Back Next > Cancel

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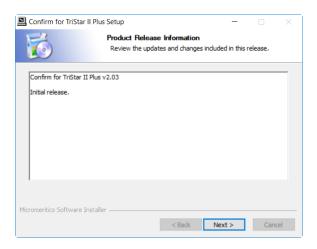
- 13. If prompted for calibration files, insert the calibration media that shipped with the analyzer.
- 14. Click **Browse** to locate and select the *[calibration]* directory. Click **Next**. If not prompted for calibration files, skip this step.

12	Calibration File Installation						
	Specify the directory containing the calibration files for analyzer S/N 217.						
The calibration file ca	I217.dat was not found in the currently selected directory.						
Click Browse to locate the directory containing the calibration files. If the calibration files are located on another CD then:							
1. Remove this se	etup CD.						
2. Place the CD f	or analyzer S/N 217 in the CD drive.						
	drive light stops blinking press the Browse button and locate the y on the CD that contains the calibration files.						
If the AutoPlay	dialog opens, you may close it or ignore it.						
Install calibration file	es for S/N 217 from this location						
	Browse						
Micromeritics Software Inst	alier ———						
	<back next=""> Cancel</back>						

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

Analyzer S/N 217 Installed Press Next to continue.	
Analyzer S/N 217 was successfully installed.	
Micromeritics Software Installer < Back Next >	Cancel

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.
 - a. 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.

	Completing the The Setup
	Your computer must be restarted in order to complete the installation of the software. Do you want to reboot now?
	Reboot now
为	I want to manually reboot later
	🕼 Create a desktop icon
	www.micromeritics.com
	< Back Finish Cancel

 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 (<u>www.micromeritics.com</u>).

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.

Iusrmgr - [Local Users and Grou	ıps (Local)]		-	×
File Action View Help				
🗢 🔿 📅 🗟 🖬				
Local Users and Groups (Local)	Name	Actions		
Groups	🔛 Users	Local Users and Groups (Loca	l)	•
Groups	Groups	More Actions		•

CREATE USER ACCOUNTS

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

	 Iusrmgr - [Local Users an File Action View Help ← ⇒ 2 2 								_	×
C	Local Liters and Groups (L Users Groups	_ocal)	Name Admin Administrator DefaultAcco Refresh	Full Name	Description Built-in account for administe A user account managed by th Built-in account for guest acco A user account managed and	erir ne ess	Actions Users More Actions	5		
			Export List							

New User		? ×	
User name: Full name: Description:			
Password: Confirm password: User must change pa User cannot change Password never expi Account is disabled	assword		
Help	Crea	ate Close	

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 pass- word must meet the minimum requirements policy set by your com- pany.
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.

lusrmgr - [Local Users a	and Group	ps (Local)\Grou	os]					-	×
File Action View Hel	p								
🗢 🄿 🙍 🖬 🗟 🗟	?								
Local Users and Groups	(Local)	Name		Description	^	Actions			
		Access Cor		Members of this group can remot		Groups			•
Groups		Administra		Administrators have complete and		More Action:	s		•
		🌆 Backup Oj	perators	Backup Operators can override sec					
X	Now G	Group_	iic Operat	Members are authorized to perfor					
	INCW C	stoup_	COM Users	Members are allowed to launch, ac					
	View	>	eaders	Members of this group can read e					
				Guests have the same access as m					
	Refres	sh	ninistrators	Members of this group have comp	~				
	Export	t List		internetie er ans greap nate compa		1			
	Help								

New Group			?	×
Group name: Description: Members:				
Add	Remove			
Help		Create	Cla	se

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.

mic_2390_analyst l	Properties			?	×	
General						
	90_analyst					
Description:	Analyst Group for Micromentics Gemini 2390					
Members:						
		Changes to a	user's amun m	emberebi		
Add	Add Remove Changes to a user's group membership are not effective until the next time the user logs on.					
	ОК	Cancel	Apply	Help)	

4. Click Add.

Select Users, Computers, Service Accounts, or Groups	×
Select this object type: Users, Service Accounts, or Groups	Object Types
From this location:	Locations
Doris Wilson	Check Names
Advanced OK	Cancel

- 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			