SURFACE AND CATALYST CHARACTERIZATION ANALYZER



# micromeritics®

# PRE-INSTALLATION INSTRUCTIONS AND CHECKLIST



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# CORPORATE PROFILE

Micromeritics Instrument Corporation is the world's leading supplier of high-performance systems to characterize particles, powders and porous materials with a focus on physical properties, chemical activity, and flow properties. Our technology portfolio includes: pycnometry, adsorption, dynamic chemisorption, particle size and shape, intrusion porosimetry, powder rheology, and activity testing of catalysts. The company has R&D and manufacturing sites in the USA, UK, and Spain, and direct sales and service operations throughout the Americas, Europe, and Asia. Micromeritics systems are the instruments-of-choice in more than 10,000 laboratories of the world's most innovative companies, prestigious government, and academic institutions. Our world-class scientists and responsive support teams enable customer success by applying Micromeritics technology to the most demanding applications. For more information, please visit www.Micromeritics.com.



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# **ABOUT THIS MANUAL**



All references to 3500, Flex, or Flex Series in this document encompass the Flex, 3Flex, and Flex Confirm environments unless otherwise noted.

The following symbols or icons indicate safety precautions and/or supplemental information and may appear in this manual:



**NOTE** — Notes contain important information applicable to the topic.



**CAUTION** — Cautions contain information to help prevent actions that may damage the analyzer or components.



<u>WARNING</u> — Warnings contain information to help prevent actions that may cause personal injury.

# CFR Note

**NOTE** — Notes that apply to 21CFR11 environments only (Confirm applications).

Dynamic Analysis and Chemisorption options are not applicable when the software is installed in 21CFR11 environments.



# GENERAL SAFETY



Do not modify this instrument without the authorization of a Micromeritics service personnel.



Toxic or flammable gases require proper venting of exhaust.



Use caution in the areas where this symbol is displayed on the instrument — such as the heating mantles and furnace. These surfaces may be hot and could cause serious burns. Use the gloves supplied in the accessories kit.

Any piece of laboratory equipment can become dangerous to personnel when improperly operated or poorly maintained. All employees operating and maintaining Micromeritics instruments should be familiar with its operation and should be thoroughly trained and instructed on safety.

- Read the manual for any special operational instructions for the instrument.
- Know how the instrument functions and understand the operating processes.



- Wear the appropriate personal protective equipment when operating this instrument such as eye protection, lab coat, protective gloves, etc.
- When lifting or relocating the instrument, use proper lifting and transporting devices for heavy instruments. Ensure that sufficient personnel are available to assist in moving the instrument. The Flex weighs approximately 103 - 106 kg (227 - 234 lb) depending on configuration.
- Always pay attention to the safety instructions provided on each label affixed to the instrument and do not alter or remove the labels. When inspecting the instrument, ensure that the safety labels have not become worn or damaged.
- The Flex has a safety shield. Ensure it is in place when operating the instrument.
- Proper maintenance is critical to personnel safety and smooth instrument operation and performance. Instruments require regular maintenance to help promote safety, provide an optimum end test result, and to prevent costly down time. Failure to practice proper maintenance procedures can lead to unsafe conditions and shorten the life of the instrument.
- Improper handling, disposing of, or transporting potentially hazardous materials can cause serious bodily harm or damage the instrument. Always refer to the MSDS when handling hazardous materials. Safe operation and handling of the instrument, supplies, and accessories is the responsibility of the operator.



## INTENDED USE

Micromeritics Flex Surface Characterization Analyzer is a fully automated one, two or three station instrument capable of high-performance physisorption and chemisorption analyses with superior accuracy, resolution, and data reduction.



The instrument is intended to be operated by trained personnel familiar with the proper operation of the equipment recommended by the manufacturer as well as relevant hazards involved and prevention methods. All use, other than that described in this manual, is seen as unintended use and can cause a safety hazard.



The instrument is intended to be used as per applicable local and national regulations.



#### **TRAINING**

It is the responsibility of the customer to ensure that all personnel operating or maintaining the equipment participate in training and instruction sessions. All personnel operating, inspecting, servicing, or cleaning this instrument must be properly trained in operation and machine safety before operating this instrument.

# ENVIRONMENTALLY FRIENDLY USE PERIOD

**Hazardous Substances Table** 

	Hazardous Substances								
Part Name	Lead (Pb)	Mercury (Hg)	Cadmium (Cd)	Hexavalent Chromium (Cr (VI))	Polybrominated biphenyls (PBB)	Polybrominated diphenyl ethers (PBDE)			
Cover	x	О	О	О	О	o			
Power Supplies	x	О	О	О	o	o			
Printed Circuit Boards	x	O	0	O	o	O			
Cables, Con- nectors & Transducers	x	0	0	O	o	O			

- o Hazardous substance is below the specified limits as described in SJ/T11363-2006.
- x Hazardous substance is above the specified limits as described in SJ/T11363-2006.

The Environmentally Friendly Use Period (EFUP) for all enclosed products and their parts are per the symbol shown here, unless otherwise marked. Certain parts may have a different EFUP (for example, battery modules) and so are marked to reflect such. The Environmentally Friendly Use Period is valid only when the product is operated under the conditions defined in the product manual.





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# 1 Pre-installation Document Overview



If a Micromeritics Service Technician performs this installation, additional charges apply. Please see <u>Contact Us on page iv</u> for information on how to contact Micromeritics.

This document describes how to prepare a site for installation of the Flex for both standard and 21 CFR Part 11 (Confirm) environments. If Micromeritics will be performing this installation, when the enclosed procedures have been completed, return the signed and dated form to Micromeritics as outlined in <u>Dates and Signatures</u> — <u>All Environments on page 6 - 1</u>. If unsure about any part of this document or the checklist, contact the Micromeritics Service Department for clarification.

The following chart indicates the applicable sections for your type of installation:

Section	Installation Type		
	Std	Cfr	
Pre-installation Document Overview above.	✓	✓	
<u>Pre-installation Instructions on page 2 - 1</u> . Contains instructions to help analyze the installation site.	<b>✓</b>	<b>✓</b>	
<b>Pre-installation Checklists on page 3 - 1.</b> Contains questions and a checklist for the installation site.	<b>✓</b>	<b>✓</b>	
<u>Pre-installation Instructions — 21CFR11 Environments on page 4 - 1</u> . Contains information to help analyze the installation site for 21 CFR Part 11 environments.		<b>✓</b>	
<u>Pre-installation Checklist</u> — <u>21CFR11 Environments on page 5 - 1</u> . Contains questions and a checklist for the installation site for 21 CFR Part 11 environments.		<b>✓</b>	
<u>Dates and Signatures — All Environments on page 6 - 1</u> . For use when Micromeritics will be performing this installation. Read this entire document carefully. Complete all checklists. Sign and return the form in this section to Micromeritics. Micromeritics will contact you to confirm an installation date.	<b>✓</b>	<b>✓</b>	



# MICROMERITICS INSTALLED INSTRUMENTS ONLY

#### APPLICATION RELATED ISSUES

To ensure a thorough installation, it will be helpful for Micromeritics to know which types of samples will be tested. If known, list them in <u>Application Related Issues Checklist on page 3 - 5</u>.

Please advise Micromeritics if samples require any pretreatment. If required, do you have the proper equipment to pretreat your samples? Micromeritics offers application assistance through our materials analysis laboratory (Micromeritics Particle Testing Authority).

#### HAZARDS AND PRECAUTIONS

Inform Micromeritics of any on-site conditions that may present hazards to Micromeritics employees or equipment. Advise Micromeritics of any precautions that need to be taken.

#### SAFETY MEASURES

Inform Micromeritics of any safety equipment, requirements, or procedures necessary for Micromeritics employees to enter and install the system at your facility.

#### Personnel Security Clearance

If security clearances, insurance certificates, or any other special arrangements are required for Micromeritics employees to enter your facility, see <u>Personnel Security Clearance Checklist on page 3 - 5</u> to explain. Inform Micromeritics how much advance notice you require to obtain clearance.

# PROJECTED INSTALLATION DATE

Read this entire document carefully. Complete all checklists in this document. Sign and return all checklists and the form in <u>Dates and Signatures</u> — <u>All Environments on page 6 - 1</u> to Micromeritics. Micromeritics will contact you to confirm an installation date.



# **2 Pre-installation Instructions**

#### UNPACKING AND INSPECTION

When the equipment is received, unpack and inspect the contents of the shipping container(s). Use the packing list to verify that all products, accessories, software (if applicable), and documentation are received intact and in the correct quantity. The shipping container(s) and contents should be inspected within a few days of receipt in the event damage or loss has occurred. Sort through all packing material before declaring missing equipment or parts.



Micromeritics recommends saving all shipping containers until installation of the equipment is complete. All shipping containers where equipment is to be declared as damaged or lost must be examined by the claims investigator prior to completion of the inspection report.

# SHIPPING DAMAGE

If equipment is damaged or lost in transit, you are required to make note of the damage or loss on the freight bill. The freight carrier, not Micromeritics, is responsible for all damage or loss occurring during shipment. If damage or loss of equipment is discovered during shipment, report the condition to the carrier immediately. Insurance claims **MUST** be made with the freight carrier, **NOT** Micromeritics.

- Keep all software, manuals, and accessories with the equipment.
- Report any shipping damage immediately to the carrier and follow their directions.
- Report missing or wrong parts to Micromeritics, in addition to any shipping damage, only after filing a claim with the carrier.
- Micromeritics will NOT file a claim for shipping damage.
- Do not discard shipping boxes and containers until installation is complete. If space is available, it is recommended that shipping containers be saved for future use in the event of return to factory for repair.



## ANALYZER SPACE

An unobstructed lab work space that will accommodate the following specifications is needed:



**Physisorption** 



Chemisorption

#### **Analyzer**

Height 112 cm (44 in.)
Width 57.25 cm (23 in.)
Depth 61 cm (24 in.)
Weight 84 kg (185 lbs)

#### **Computer and Printer**

Width 96.5 cm (38 in.) Approx.

#### **Gas Supply**

1 square ft (0.1 square m) for each gas cylinder needed for installation. For standard installations, the cylinders must be within 6ft (2m) of the instrument.

#### **External Vacuum Pump**

Height 17 (7 in.) Approx.
Width 15 cm (6 in.) Approx.
Depth 31 cm (12 in.) Approx.

#### **Degas Unit (optional accessory)**

Width 50 cm (20 in.) Approx. Depth 40 cm (16 in.) Approx.



#### Installation Configuration

Standard installation requires the use of 1/8 in. copper or stainless steel gas supply lines, located in the instrument accessories kit.

A nonstandard installation will be created if another gas supply line is used or if the gas cylinders cannot be placed within 6 ft (2 m) of the analyzer. There may be additional costs associated with a nonstandard installation. Please contact the Micromeritics Service Department at 1-770-662-3666 to discuss a nonstandard installation.

# **COMPUTER SYSTEM**

We recommend purchasing the computer system from Micromeritics. Micromeritics thoroughly tests operating systems with the Micromeritics applications and offer technical support and maintenance for the computers we provide. For analyzers not installed by Micromeritics, please note:



- The labor and expense costs associated with delays traceable to a computer system not purchased from Micromeritics are not part of a standard installation.
- Micromeritics is not responsible for providing assistance for the connection to a company network or LIMS.
- During installation, Administrator rights will be required to make changes to the Ethernet settings. If access cannot be granted to the Service Technician, an IT representative must be readily available to make these changes or additional charges may apply.



# **Computer Requirements**

Operating System	Windows 7 Professional or higher operating system is recommended for the best user experience. For 21 CFR Part 11 environments, Windows 10 Professional or Windows 10 Enterprise or higher is required.
Desktop Installation Required	The application should not be installed on a network drive with shared access. Multiple users cannot operate the application at the same time.
	If the computer is to be connected to a network, two Ethernet ports are required. If more than one Ethernet based unit is connected to the same computer, an Ethernet switch will also be required. If a Smart VacPrep is to be used, an Ethernet switch is required.
Read/Write Permissions	All users of the application will need Read/Write permission to all directories and subdirectories where the application is installed. For 21 CFR Part 11 environments, permission may be limited to the installation directory.
Drives	USB port

Due to continuous improvements, specifications are subject to change without notice.



## **ENVIRONMENTAL FACTORS**

#### **POWER**

The Flex is designed to operate with a universal input power supply (100/115/230VAC) at 50/60 Hz. Noise-free power of the correct voltage and frequency, with a safety earth ground, should be available through a standard wall receptacle. The power outlet should be able to supply 15 amps @ 100 or 115VAC ±10% or 7.5 amps @ 230VAC ±10%. These requirements can be checked by using a circuit analyzer (available at most hardware or electronic supply houses) or a multimeter. There should also be sufficient outlets for the analyzer, Smart VacPrep (if purchased), dry roughing pump, computer, monitor, printer, and any other peripheral devices.

The instrument should be connected to a switch which meets relevant requirements of IEC 60947-3 or a circuit breaker which meets the relevant requirements of IEC 60947-2.



The analyzer and peripheral devices **must** be installed on their own dedicated power line. Other devices — such as motors, generators, or ovens — **should not** be placed on the same power line.



Replacement power supply cords must be rated for the specifications stated above.

# TEMPERATURE AND HUMIDITY

Temperature and humidity must be controlled to within:

■ Temperature: 10 to 35 °C (50 to 95 °F) operating; 0 to 50 °C (32 to 122 °F) nonoperating

■ **Humidity:** 20 to 80% relative, non-condensing

#### Do Not:

- Allow room temperature or humidity to exceed limits.
- Install the analyzer where it is exposed to direct sunlight.
- Locate the analyzer near air conditioning or heating vents.



## GAS SUPPLY



<u>For physisorption</u>, the analyzer requires dry gas to operate its valves. Dry compressed air is recommended; however, a cylinder of dry compressed air or nitrogen can be used. This gas line, from either house air or a portable compressor, must have the pressure set to 100 psi.



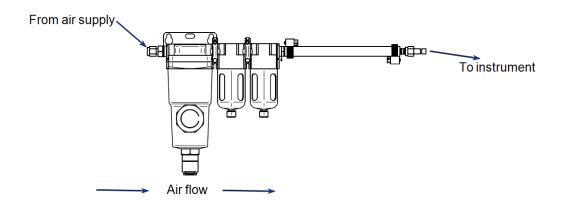
<u>For chemisorption</u>, the analyzer requires dry gas to operate its valves. Dry compressed air is recommended; however a portable compressor can be used with a chemisorption unit. This gas line must be set to 100 psi. Using a cylinder of gas (air or nitrogen) is not recommended because it will drain the cylinder of gas in a short period of time.



The analyzer requires dry gas to operate its valves. Dry compressed air is recommended; however, a cylinder of dry compressed air or nitrogen can be used. This gas line, from either house air or a portable compressor, must have the pressure set to 100 psi.

A pneumatic filter assembly is supplied in the accessories kit and is needed if clean, dry compressed air is not available. The filter assembly connects to the back of the analyzer using tubing and a 1/4 in. Swage fitting. The connection from the filter assembly to the air supply comes assembled with a 1/4 in. fitting; however, a 1/8 in. fitting is also provided.

The filter assembly must be mounted as shown to work properly. The black drain plugs on the bottom of the bowls must be pointed toward the floor.





# GAS CYLINDERS AND GAS SUPPLY LINES

- See <u>Gas for Analyzer Test on page 2 11</u> for the analytical gases needed during installation. Gas cylinders must be placed within 6 ft (2 m) of the analyzer inlet valves
- The customer is required to ensure the purity of gases.
- It is required that the 1/8 in. × 6 ft (2 m) single piece copper gas line in the analyzer accessories kit is used. Stainless steel gas lines are available from Micromeritics for use with gases that are not compatible with copper.



Gas lines not supplied by Micromeritics will not be installed by Micromeritics Service Personnel.



Gas supply lines made of materials other than copper or stainless steel may cause operational problems.

- **Do not** use gas cylinders with less than 500 psig (3549 kPag) pressure.
- Do not use any other gas lines to connect the gas supply to the analyzer except those supplied
  in the accessories kit. Use of other gas lines will result in a nonstandard installation. See <u>Install-ation Configuration on page 2 3</u>.
- **Do not** use gas purifiers; they can cause operational problems. Oxygen traps are preferred.



## GAS SUPPLY HARDWARE

Micromeritics recommends the gas regulators to be used with the analyzer be purchased from Micromeritics. The regulators Micromeritics provides have been carefully evaluated and tested to provide superior performance.



**For Chemisorption Only** - A vent line for the vacuum pump and analyzer is required. The vacuum line must exhaust to a vent hood or to the outside of the building.



If purchased from a source other than Micromeritics, please keep in mind that many commercially available gas regulators lack key features which are required for gas adsorption measurements. These vital criteria must be met:

- Cleanliness. Clean regulators designed specifically for high-vacuum service are required.
   Other regulators often contain elastomeric material or oils which can contaminate the gas.
- **High stability**. Excess pressure at the gas inlet ports to the analyzer can interfere with accurate gas dosing and flow rates. The combined change in the outlet pressure from the gas regulator, as the gas cylinder pressure decreases or as the flow rate stops, should not change more than 5 psig (34.4 kPag) from the selected setting. When the analyzer is idle for an extended period of time, such as 8 to 10 hours, this same stability of gas delivery pressures should be achieved.
- Range of pressure. The regulator output must operate from 0 to 30 psig (207 kPag).
- **Suitable sub-assemblies.** The regulator must have a shutoff or outlet isolation valve compatible with 1/8 in. or 1/4 in. Swagelok compression fittings.



To purchase regulators from Micromeritics, contact your local Micromeritics Sales Representative.



#### REGULATOR EXPANSION KITS

It is sometimes beneficial to attach more than one analyzer, and/or accessory device, or different inlet ports to a single gas supply. Any time this is done, it is critically important that there be a means of isolating, or shutting-off, each device attached to the gas supply regulator. Micromeritics recommends the use of a vacuum rated shutoff/isolation valve for this purpose.

This shutoff/isolation valve is required in order to prevent problems when changing gas cylinders or servicing any of the devices attached to the gas supply.

If the need to attach more than one inlet or one analyzer and/or accessory device is anticipated, one or more of the following regulator expansion kits must be acquired:

- **004-33601-00** Regulator Expansion Kit (2 outlet, 1000 psi maximum). This kit contains one T fitting, two vacuum rated shutoff valves, and other necessary hardware. This expansion kit allows gas to be provided to two inlets.
- **004-33601-01** Regulator Expansion Kit (3 outlet, 1000 psi maximum). This kit contains one cross fitting, three vacuum rated shutoff valves, and other necessary hardware. This expansion kit allows gas to be provided to three inlets.



# LABORATORY EQUIPMENT AND SUPPLIES

# LIQUID NITROGEN

Ensure liquid nitrogen is available in sufficient quantities. A minimum of 10 liters is required for starting an analysis.

- For installation, there **must** be an adequate supply of liquid nitrogen.
- **Do not** use liquid nitrogen that is either blue (a sign of oxygen contamination) or not clear.

# ANALYSIS EQUIPMENT AND SUPPLIES

Since the analysis results are expressed in units of surface area per gram of sample, the true mass of the sample must be known. This requires an analytical balance with the capability of 100 grams measurement and 0.1 mg readability.

In order to obtain accurate analysis results, the sample tubes must be clean. The following items are suggested for cleaning sample tubes:

- Alconox or similar laboratory detergent
- Balance for weighing sample
- Brush
- Clean, dry compressed air or dry nitrogen
- Drying oven

- Isopropyl alcohol
- Sink
- Small plastic tub for detergent solution
- Ultrasonic bath



# GAS FOR ANALYZER TEST

To verify proper analyzer operation and to train users, Micromeritics representatives will analyze the reference material provided in the analyzer accessories kit.

The following gases are required in order to analyze the reference materials. If these gases are not available, Micromeritics representatives will only be able to perform a limited number of analyzer tests during installation and operator training.



All gases require the indicated purity.

All analyzer types		Chemical adsorption units
(CGA 580) N <sub>2</sub> (CGA 580) He	99.999% 99.999%	All gases listed to the left and:  (CGA 350) H <sub>2</sub> 99.999%  (CGA 350) CO 99.990%  Pre-mix 10% CO in helium (required for Dynamic Chemical Adsorption units and TCD units only)

Any additional gases that may be used after the installation is complete can be connected by the Micromeritics representative.

# **DEGAS UNIT**

Although some samples can be degassed on the analyzer, it is highly recommended that a separate degas unit — such as a Smart VacPrep — is available to ensure that proper degassing of all sample types can be performed. Using a degas unit avoids moisture and contamination in the analyzer.



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# 3 PRE-INSTALLATION CHECKLISTS

For each question, circle **Yes** if the condition applies to your laboratory or **No** if it does not. When this *Pre-installation Checklist* has been completed, see <u>Dates and Signatures</u> — <u>All</u> <u>Environments on page 6 - 1</u>. Sign and date the form, then send it along with all completed checklists to Micromeritics.

# UNPACKING AND INSPECTION CHECKLIST

Unpacking and Inspection	Initial / Date		
Have the shipping cartons been unpacked and their contents inspected?	Υ	N	
Was there any shipping damage?	Υ	N	
■ If <b>Yes</b> , has a claim been filed with the freight carrier?	Y	N	
Were all items on the packing list received?	Υ	N	
■ If <b>No</b> , has has Micromeritics been notified?	Υ	N	

# ANALYZER SPACE CHECKLIST

Analyzer Space			Initial / Date
Can the area also accommodate the Smart VacPrep or VacPrep?	Y	N	
Will there be adequate space to easily access the gas lines, power supply lines, and sufficient clearance for maintenance and inspection?	Y	N	



# INSTALLATION CONFIGURATION CHECKLIST

Gas and Gas Supply Lines	Initial / Date		
Will 1/8 in. copper gas supply lines (supplied with the analyzer for standard installation) be used?	Y	N	
■ If <b>No</b> , have 1/8 in. stainless steel gas supply lines been ordered and received from Micromeritics?	Y	N	

# **ENVIRONMENTAL FACTORS CHECKLIST**

Environmental Factors	Initial / Date		
Is power available with the correct voltage and frequency, and a safety earth ground?	Y	N	
Are temperature and humidity controlled within specifications?	Υ	N	
Are hazards present or precautions necessary in area of installation?			
■ If <b>Yes</b> , please explain:			
Are safety measures required?	Υ	N	
■ If <b>Yes</b> , please explain:			
For chemisorption units, are exhaust lines available?	Y	N	



# GAS SUPPLY CHECKLIST

Gas Supply			Initial / Date
A clean compressed air supply at 100 ±10 psig with a 1/4 in. (recommended) or 1/8 in. fitting on a dedicated line is required. Will it be available at the instrument?	Y	N	
Are gas cylinders located within 6 ft (2 m) of where the instrument will be installed?	Y	N	
Were gas regulators purchased from Micromeritics?	Y	N	
■ If <b>No</b> , do your gas regulators meet Micromeritics' specifications?	Y	N	

Required Gases				Initial / Date	
Are the following <b>required</b> gases available? The installation will not be scheduled until these gases are available:					
All instrument types:					
(CGA 580) N <sub>2</sub>	99.999%	Y	N		
(CGA 580) He	99.999%	Y	N		
Chemisorption instrume	nts (in addition to the above gases):				
(CGA 350) H <sub>2</sub>	99.999%	Y	N		
(CGA 350) CO	99.990%	Y	N		
Pre-mix 10% CO in helium units and TCD units only)	(required for Dynamic Chemisorption	Y	N		

Additional Gases
Additional gases for use after installation can be connected by the Micromeritics service representative. Please list any gases that will be available for connection during installation.
Initial / Date



# **COMPUTER SYSTEM CHECKLIST**

			Initial / Date
Was the computer purchased from Micromeritics?	Υ	N	
■ If <b>No</b> , does the computer meet Micromeritics' minimum requirements?	Y	N	
Will the computer be connected to the local network?	Υ	N	
■ If <b>Yes</b> , will two Ethernet ports be available during the installation?	Y	N	
Will there be more than one Micromeritics Ethernet based analyzers connected to this computer?	Υ	N	
■ If <b>Yes</b> , will an Ethernet switch be available during the installation?	Y	N	
Will the Micromeritics Service Engineer have Administrator rights to the computer?	Υ	N	
■ If <b>No</b> , will an IT representative be available?	Y	N	
All application users are required to have read/write permission to all directories and subdirectories where the application is installed. Will these permissions be set prior to installation?	Υ	N	

# **DEGAS UNIT CHECKLIST**

Degas Unit		
Which degas unit did your purchase?		
■ Smart VacPrep	Y	N
■ FlowPrep	Y	N
■ VacPrep	Y	N



# LABORATORY EQUIPMENT AND SUPPLIES CHECKLIST

Laboratory Equipment and Supplies			Initial / Date
Are sufficient quantities of liquid nitrogen available?	Υ	N	
Are sufficient quantities of isopropyl alcohol available?	Y	N	
Is a balance available for weighing samples?	Y	N	
Is a drying oven or sample degasser available?	Y	N	

# **APPLICATION RELATED ISSUES CHECKLIST**

Application Related Issues			Initial / Date
What types of samples will be tested?			
lı	nitial /	Date:	
Will these samples require pretreatment?	Υ	N	
Is a vacuum oven available to pretreat samples?	Υ	N	
Will any application assistance from Micromeritics Particle Testing Authority be required?	Y	N	

# PERSONNEL SECURITY CLEARANCE CHECKLIST

Security Clearance		
Are there any special arrangements required concerning security clearance?	Y	N
■ If <b>Yes</b> , please explain:		
Initial / Da	te:	



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# 4 Pre-installation Instructions — 21CFR11 Environments

Use the <u>Users and Groups Worksheet for 21CFR11 on page 5 - 3</u> to log user names and assigned groups.

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.

If the computer will be connected to a LAN, the network/Windows administrator must be available to install the network connection. Also, if the analyzer files need to be accessible to a LIMS, file location will need to be discussed during installation.

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	<ul> <li>The default Developer group name is mic_[analyzer model number]_developer. Members of the Developer group:</li> <li>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.</li> <li>can run an analysis.</li> <li>can also be assigned Administrator rights which control the user profiles.</li> </ul>
Analyst Group	The default Analyst group name is  mic_[analyzer model number]_analyst. Members of the Analyst group:  have access to the Basic 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	√*	<b>√</b> *
Can overwrite, rename, or delete existing files in the data directory	<b>√</b> *	<b>√</b> *
Can perform diagnostics	✓	✓
Can perform calibration	✓	✓
Can view and print the system audit trail	✓	✓
Can manage libraries	✓	✓
Can change system units and gas selections	✓	✓
Browse outside of the Confirm installation location	✓	
Can add log entries	✓	<b>√</b> *

<sup>\*</sup> With administrative privileges only.



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# 5 Pre-installation Checklist — 21CFR11 Environments

For each question, circle **Yes** if the condition applies to your laboratory or **No** if it does not. When this *Pre-installation Checklist* has been completed, see <u>Dates and Signatures</u> — <u>All</u> <u>Environments on page 6 - 1</u>. Sign and date the form, then send it to Micromeritics.

# PERSONNEL REQUIREMENTS

Network Administrator			Initial / Date
Name:			
Will the computer be connected to a LAN? If <b>Yes</b> , does the network administrator have the ability to:	Y	N	
■ connect the computer to a network?	Y	N	
■ correct network connection problems?	Y	N	
■ set necessary network drive and directory access?	Y	N	
Will the analyzer need to be accessible to a laboratory information application? If <b>Yes</b> :	Y	N	
does the application administrator have the necessary file permissions?	Y	N	
will the network administrator be available during install- ation?	Y	N	

Confirm Administrator			Initial / Date
Name:			_
Will the Confirm Administrator:			
have administrative privileges?	Y	N	
have a basic understanding of Windows groups and Windows users?	Y	N	
■ be available during installation?	Y	N	



Software User			Initial / Date
Name:			
Will the software user:			
have the ability to create and manage Windows users and groups?	Y	N	
■ have Windows Administrator access?	Y	N	
■ be available the first and last day of installation?	Y	N	

# **USER INFORMATION REQUIREMENTS**

Function	Initial / Date		
Has the <u>Users and Groups Worksheet for 21CFR11 on the</u> <u>facing page</u> been completed?	Υ	N	



# USERS AND GROUPS WORKSHEET FOR 21CFR11

Micromeritics Confirm application:	Developer	Analyst
User Name  Full Name		



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# 6 DATES AND SIGNATURES — ALL ENVIRONMENTS



All checklists and this completed form should be returned only if Micromeritics will be performing this installation.

### PROJECTED INSTALLATION DATE

This is not a commitment for a specific installation date. After reading the site preparation requirements in this document, enter a date your site will be prepared and a preferred date for installation. After returning the checklist and signed form to Micromeritics, your Micromeritics representative will contact you to confirm an installation date.

When would installation be most convenient? Date: \_\_\_\_\_/\_\_\_\_/

# COMMITMENT STATEMENT AND SIGNATURE FORM

I have read this document and understand my responsibilities regarding preparations for the installation of our analysis system. I believe this site is ready for the system to be installed.

Signature:		Date:		
Name (Printed):				
Title (Printed):				
Company:				
City / State / Zip:				
Phone Number:		Fax Number:		
E-mail:				
Analyzer:	Model:	Serial No.:		
Is the Customer Repre	esentative also the E	ind User? Yes No		

#### RETURN THE COMPLETED CHECKLIST AND FORMS TO:

Micromeritics Instrument Corporation ATTN: Service Operations Manager 4356 Communications Drive Norcross, GA / USA / 30093-2901

Email: Service.Helpdesk@Micromeritics.com

Fax: 1-770-662-3604



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#### **EU DECLARATION OF CONFORMITY**

This declaration of conformity is issued under the sole responsibility of the manufacturer:

Micromeritics Instrument Corporation 4356 Communications Drive Norcross, GA 30093, USA

Hereby declares that the product:

FLEX™ SERIES Surface and Catalyst Characterization Analyzer Models: 3Flex (3500)

is in conformity with the following EU harmonization legislation:

2014/35/EU - LVD Directive 2014/30/EU - EMC Directive 2011/65/EU - RoHS Directive

and that the equipment is in conformity with the following harmonized and other appropriate standards;

#### 2014/35/EU (LVD)

**EN 61010-1:2010/A1:2019** - Safety requirements for electrical equipment for measurement, control, and laboratory use — Part 1: General requirements.

**EN 61010-2-010:2014** - Particular requirements for laboratory equipment for the heating of materials **EN 61010-2-081:2015** - Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes

#### 2014/30/EU (EMC)

**EN 61326-1:2013** - Electrical equipment for measurement, control and laboratory use — EMC requirements — Part 1: General requirements

**EN 61000-3-2:2014** - Part 3-2: Limits — Limits for harmonic current emissions (equipment input current  $\leq$  16 A per phase)

**EN 61000-3-3:2013** - Part 3-3: Limits — Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current  $\leq$  16 A per phase and not subject to conditional connection

#### 2011/65/EU (RoHS)

EN 63000:2018 - Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances

Name: John McCaffrey, Ph.D.

Title: Vice President, R & D

Signature:

Date of issue: <u>04/14/2021</u>

Location: Norcross, GA USA