

microPHAZIR Analyzer

User Guide

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Contents

Preface 1		
	Safety and Special Notices	1
	General Safety Instructions	2
	Unsafe Operation	3
	Contacting Us	3
Chapter 1	Getting Started with the microPHAZIR Analyzer	
•	microPHAZIR Analyzer Component Parts	
	Carrying case	
	Using Optional Accessory Adaptors	
	Powering the Unit	
	Opening and Closing the Access Door	
	Changing the Battery	
	Charging the Battery	
	Installing the Vial Holder	13
	Using the Bar Code Reader	
	Using the Keyboard	15
	Changing System Settings	15
	Using Configuration Files	
Chapter 2	Logging In and User Privileges	17
	Login Options	
	Logging in with a Password	
	Changing Your Login Password	
	User Access Levels	
Chapter 3	Best Practices	21
onuptor o	The Key to a Good Scan	
	Choosing the Proper Adaptor	
	Best Practices Tables	
	Dest Hactices Lables	2.

ii

Chapter 4	Running Methods, Reviewing Results, and Syncing Files25			
	Overview	25		
	Pass/Fail scan results			
	Identification scan results			
	Quantitative scan results			
	Loading Libraries and Methods			
	Running a Method			
	Running methods using a barcode scan			
	Running methods manually.			
	Discover Information for a Fail Result.			
	Adding a Note to a Result Screen			
	Reviewing Results			
	Syncing Files			
Chapter 5	Creating Signatures and Methods	35		
oapro. o	What are Methods and Signatures?			
	Best Practices for Acquiring Signatures			
	Obtaining representative samples for the method			
	Option for collecting methods for liquid samples			
	Acquiring Signatures			
	Building Libraries			
	Importing Libraries			
Chapter 6	Using the microPHAZIR Admin Tool	43		
	Overview			
	Before Installing microPHAZIR Admin			
	Installing microPHAZIR Admin			
	Who Can Use microPHAZIR Admin			
	Connecting to microPHAZIR Admin	45		
	Managing Methods			
	Adding libraries and methods to the instrument	47		
	Removing libraries and methods from the instrument	48		
	Editing libraries and methods			
	Viewing method details	49		
	Editing IDs	50		
	Managing barcodes	51		
	Managing Data	52		
	Selecting an Archive Destination	53		
	Formatting Reports	53		
	Exporting Configuration Files			
	Importing Configuration files	54		
	Managing User Accounts	55		
	Adding, Editing, or Deleting User Accounts	55		

	Configuring System Settings	58
	Configuring Login Settings	58
	Configuring PQ Certification	59
	Configuring OQ Certification	60
Chapter 7	Maintaining Your Unit	61
-	Running a Self Test	61
	Rebooting the Unit	63
	Cleaning and Decontaminating the Unit	63
	Replacing the Light Bulb	
	Obtaining Replacement Parts	65
	Getting Help with Problem Results	65
	Creating a Diagnostics File	66
	Returning the Unit for Service	66
	Running the Calibrate Reference Test	67
	Running the Operational Qualification Test	68
	Viewing the Serial Number and Software Version	70
Appendix A	Using the Method Generator	71
	Installing and Registering Method Generator	71
	Using Secure Mode and Audit Logs	
	Login and User Privileges	73
	Collecting Data to Create Application Scripts	74
	Evaluating Spectra in Method Generator	74
Appendix B	Limited Warranty	
Appendix C	Regulatory Statements	79
	FCC and Industry Canada Statements	79
	Export Regulation Statements	79
	Statements	80
	European WEEE	80

Contents

Preface

The Thermo Scientific microPHAZIR™ analyzer is an integrated handheld spectral analyzer that includes:

- A near infrared (NIR) spectrometer
- Light source
- Computer
- Color LCD display
- Batteries

The analyzer is designed to analyze diffuse reflection measurements from solids, powders, or other reflective materials in a wide range of applications. An accessory for transmission of materials such as liquids is available as well.

The analyzer uses a scripting language to define applications that can be operated by users with minimal training and little or no spectroscopy experience. Separate scripts are written for each application, enabling a single instrument to function successfully for many applications in many fields.

This manual provides detailed operating instructions and information on the operation and care of the microPHAZIR analyzer.

Safety and Special Notices

Make sure you follow the precautionary statements presented in this guide. The safety and other special notices appear in boxes.

This document contains the following types of safety and special notices:



CAUTION Highlights hazards to humans, property, or the environment. Each CAUTION notice is accompanied by an appropriate CAUTION symbol.

IMPORTANT Highlights information necessary to prevent damage to software, loss of data, or invalid test results; or might contain information that is critical for optimal performance of the system.

Note Highlights information of general interest.

Tip Highlights helpful information that can make a task easier.

General Safety Instructions



CAUTION Read this section carefully before connecting and operating the analyzer and the accessories.



CAUTION Follow the general safety precautions and special safety instructions in this manual to guarantee the best possible operating safety. If the equipment is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired.

The equipment is rated IP X0 per IEC 60529. The analyzer and its accessories comply with the relevant safety regulations. This instrument complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This instrument may not cause harmful interference, and (2) this instrument must accept any interference received, including interference that may cause undesired operation.

Repairs must be performed by authorized personnel only. Improper repairs could result in considerable damage to the analyzer and possible danger to the user. All components, including the lithium batteries, shall be disposed of properly, as required by all local authorities and jurisdictions.

Use only the battery pack that is provided by the manufacturer. This battery pack has its own protection against short circuit, over charging, and excessive discharging. The battery pack should be charged only with a suitably certified or approved battery charger.

Unsafe Operation

If the analyzer is damaged or not functioning properly, it should be switched off and not used until it has been properly repaired or replaced. Operation of an improperly functioning or damaged analyzer can result in incorrect readings and even danger to the operator.

Conditions that may harm the instrument:

- Steam
- High humidity (moisture condensing conditions)
- Extreme ambient temperatures below 40°F (5°C) or above 125°F (50°C)
- Strong electromagnetic (motors or transformers) or electrostatic fields
- Strong vibrations and impacts
- Contact with oxidative, corrosive and caustic atmospheres such as, but not limited to chlorine gas, hydrochloric acid, ammonia
- Contact with oxidative, corrosive and caustic liquids, such as, but not limited to concentrated hydrogen peroxide, sulfuric acid, aqueous sodium hydroxide

Conditions that exceed the instrument's design:

- Immersion in water and electrically-conductive liquids
- Combustible atmospheres due to flammable gases
- Burying in dirt
- Long-term exposure to solvent vapors, including methylene chloride
- Flammable liquids, e.g. kerosene, gasoline, diesel, oil, alcohols, ketones

Failing to follow these instructions may result in harm to the instrument or user. If the instrument is damaged due to exposure to any of these conditions, even occasional, your warranty will be voided. Please contact Thermo Scientific if you require modifications to permit the instrument to work in these harsh conditions.

Contacting Us

Contact Thermo Fisher Scientific any time for information or assistance.

(1104) 1 000 07/ 1000

Telephone	(USA)	1-800-3/4-1992
	(International)	+1-978-642-1100
Email		support@chemid.thermofisher.com
Website		www.thermoscientific.com/chemID-support
Mail		2 Radcliff Road, Tewksbury, MA 01886

Preface Contacting Us

Getting Started with the microPHAZIR Analyzer

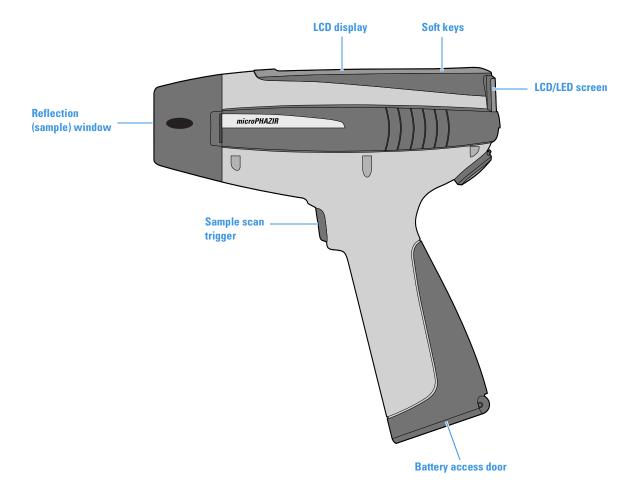
Contents

- microPHAZIR Analyzer Component Parts on page 6
- Using Optional Accessory Adaptors on page 9
- Powering the Unit on page 11
- Opening and Closing the Access Door on page 11
- Changing the Battery on page 12
- Charging the Battery on page 12
- Installing the Vial Holder on page 13
- Using the Bar Code Reader on page 14
- Using the Keyboard on page 15
- Changing System Settings on page 15
- Using Configuration Files on page 16

microPHAZIR Analyzer Component Parts

The microPHAZIR analyzer was developed using Thermo Scientific's MEMS (Micro-Electro-Mechanical System) technology, which enables the construction of small spectrometers that have no moving parts and use minimal power.

Figure 1. microPHAZIR components



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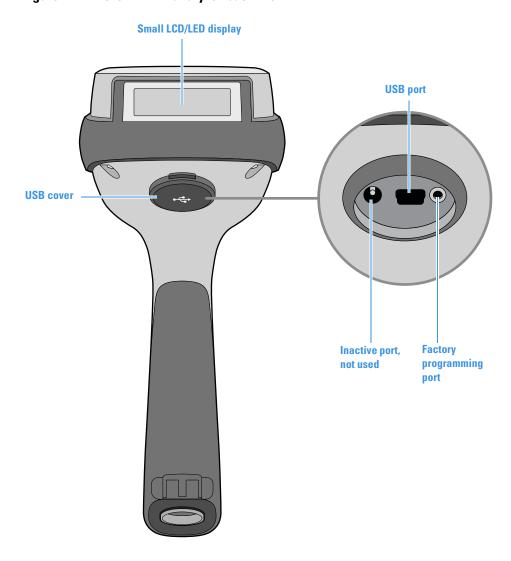


Figure 2. microPHAZIR analyzer back view

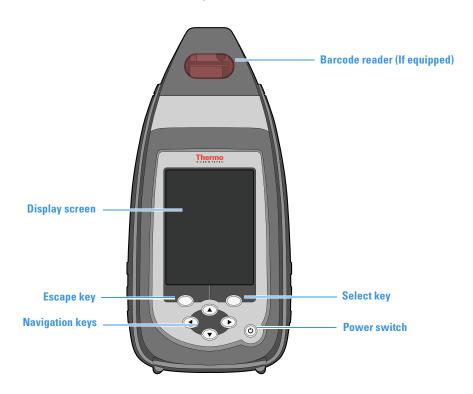


Figure 3. microPHAZIR analyzer top view

Carrying case

The following items are included in the microPHAZIR case:

- 1microPHAZIR analyzer
- 1 USB cable
- 1 spare microPHAZIR rechargeable battery (a battery is also installed in the microPHAZIR analyzer
- 1 battery charger
- 1 0.050-inch Allen key
- 1 Phillips screwdriver
- 1 CD or printed operating manual
- 1 spare bulb
- 1 reference holder
- 1 white reference (Fluorilon)

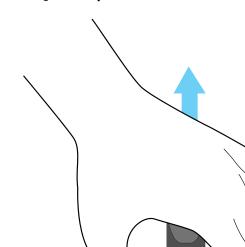
Using Optional Accessory Adaptors

You attach adaptors by pressing them onto the instrument nose until the two side clips lock into the slots (see Figure 4).

The adaptor is removed by squeezing the two metal release arms simultaneously, as shown in Figure 5. The adaptor will release and slide off the nose.

Figure 4. Attaching the adaptor





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Figure 5. Removing the adaptor

Powering the Unit

The microPHAZIR analyzer is powered by an Inspired Energy 7.2V Lithium Ion rechargeable battery providing approximately 5.8 hours in normal use. After you turn on power, the instrument starts up and then loads software in about 30 seconds.

Next the light source turns on and performs an initial calibration. The tungsten light source is harmless and requires no precautions.

The instrument has three power states: On, Standby (a power-saving mode), and Off.

Note The instrument enters Standby mode if it remains idle for several minutes. If this occurs, the user must log in again.

To turn on the instrument

- 1. Install a battery in the instrument.
- 2. Press and hold the Power key until the display backlight turns on, then release the key.

❖ To turn off the instrument

Press the Power key for several seconds.

Opening and Closing the Access Door

The access door is designed to securely seal the battery compartment, to protect it from contaminants.



CAUTION When the access door on the bottom of the instrument is open, the environmental seal is broken. The system must be sealed to provide water and dust resistance.

❖ To open the access door

Place your thumb on the access door switch and pull down.

❖ To close the access door

Press the access door shut until you hear it click.

Changing the Battery

The microPHAZIR battery can be exchanged without tools. Change the battery when the low-battery message appears in the display, or the screen does not illuminate. Turn the instrument off before removing the battery.



Do not remove the battery when the microPHAZIR analyzer is turned on. Doing this may damage the system software, causing the instrument to behave unpredictably or even to fail to boot up. If the software is damaged, you will need to return the instrument for servicing.

❖ To change the battery

- 1. Turn off the instrument by pressing the Power key for several seconds.
- 2. Open the access door.
- 3. Remove the battery by opening the latch on the bottom of the handle and pulling the battery tab.
- 4. Slide the new battery into the handle and pushing firmly into place.
- 5. Close the latch on the bottom of the handle.

Charging the Battery

It takes approximately 4 hours to fully charge a battery. Use only a certified or approved battery charger.

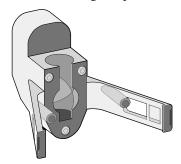
To charge the battery

- 1. Insert the battery into the battery charger.
- 2. Look at the LED indicator to determine the charge status.
 - Green flashing means the battery is charging.
 - Green solid means the battery is fully charged.
 - Red indicated error.

Tip The rechargeable battery performs best if it is kept charged and not allowed to discharge completely.

Installing the Vial Holder

The vial holder provides optimal stability during lengthy scans. It is useful for acquiring signatures and running samples.



❖ To install the vial holder

- 1. Align the vial holder with the light aperture on the nose of the instrument.
- 2. Press the vial holder into the instrument until it is seated.

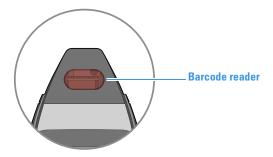


- 3. Insert the vial into the holder.
- 4. If the vial has a label, position it away from you so that it does not block the light.

To remove the vial holder, gently pull it away from the instrument.

Using the Bar Code Reader

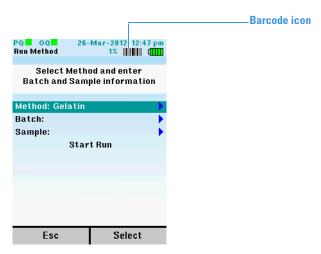
The barcode reader is located on nose of the instrument, as shown below



The barcode reader selects a method by reading the barcode associated to that method.

Note If the barcode is not recognized, a message says "barcode not found in method list".

You can use the barcode reader whenever the barcode icon is visible in the upper right corner of the Run Method screen.



To use the barcode reader

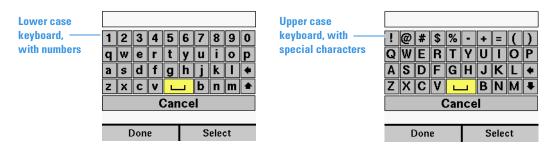
- 1. Login to the microPHAZIR analyzer.
- 2. Aim the reader at the barcode and press the microPHAZIR analyzer trigger. The red barcode scanner light shines for only a few seconds.
- 3. The instrument selects the appropriate method.

Using the Keyboard

The microPHAZIR analyzer displays a keyboard when you need to enter data into the system, such as a note.

Enter data one character at a time, using the arrow keys to navigate. When finished, select **Done**.

Figure 6. The microPHAZIR keyboard



Note Keyboard special characters are disabled when you create Sample, Batch, Library, Method or general file names. Use only alphanumeric characters when naming these files. Keyboard special characters *are* allowed for passwords.

- To enter a character, use the arrow keys to choose the character > press the Select key.
- To enter a space, select the bracket key > press the Select key.
- To delete characters, press the back arrow key.
- To enter a capital letter, select the up arrow key > press the Select key.

Tip You can bypass the keyboard and use the barcode reader to enter a Sample ID or Batch ID. See "Using the Bar Code Reader" on page 14.

Changing System Settings

Changing system settings requires Administrator privileges. See "User Access Levels" on page 20.

Note The microPHAZIR analyzer does not automatically shift from standard to daylight saving time or back. You must manually set the time to reflect the time change.

❖ To change date or time

- 1. In the Main menu, select **Tools** > press the Select key.
- 2. Select **System Settings** > press the Select key.

- 3. Select **Set Date &Time** > press the Select key.
- 4. Select Month, Day, Year, Hour, or Minutes and make changes.

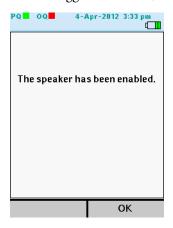


5. When you finish, select **Save.**

You can turn the scan sound on or off, depending on your work site preferences.

To enable/disable speaker

- 1. In the Main menu, select **Tools** > press the Select key.
- 2. Select **System Settings** > press the Select key.
- 3. Select **Enable/Disable Speaker**> press the Select key.
- 4. You can toggle the feature, to enable or disable the speaker.





5. When you finish, select **OK.**

Using Configuration Files

You can use configuration files to backup a system configuration, or to copy a system configuration across multiple microPHAZIR analyzer systems. See "Exporting Configuration Files" on page 54 and "Importing Configuration files" on page 54

Logging In and User Privileges

Contents

- Login Options on page 17
- Logging in with a Password on page 17
- Changing Your Login Password on page 18
- User Access Levels on page 20

Login Options

Each microPHAZIR is configured by the factory with two user accounts named **Admin** and **Operator**. The password is **default** (all lower-case). User accounts including passwords can be configured by the system administrator using the Admin Tool.

Logging in with a Password

User accounts including passwords are configured by the system administrator using the Admin Tool. The first time that you login, the password is **default** (all lower-case). After you login, you should immediately change it to a new password.

To login to the instrument

- 1. Press the trigger to login.
- 2. Select your name in the login screen > press the Select key.
- 3. Use the keyboard to enter your password. If you need help, see "Using the Keyboard" on page 15.
- 4. Select **Done** > press the Select key. When the Main menu appears, you can operate the instrument.

Changing Your Login Password

Passwords must be changed at least every 60 days. This helps to protect the instrument from unauthorized access.

- If strong passwords are used, follow the requirements in Table 1.
- If strong passwords are not used, the options include:
 - 1-15 characters
 - letters, numbers, and spaces
 - these characters !@#\$%+=()-

Developers and Administrators can change passwords via the Users tab of the microPHAZIR Admin. See "To edit a user account" on page 56. The procedure below shows how to change your password from the instrument.

❖ To change your password

- 1. In the Main menu, select **Tools** > press the Select key.
- 2. Select **Change Password** > press the Select key.
- 3. Enter your current password > select **Done**.
- 4. Enter a new password > select **Done**.
- 5. Re-enter a new password > select **Done**.

Table 1. Requirements for strong passwords

Constraint	Requirement	
Length	8 to 14 characters in length	
Required characters	At least 1 capital letter	
	At least 1 lowercase letter	
	At least one numeric character	
	At least 1 of the following characters:	
	• Exclamation point (!)	
	• At sign (@)	
	• Pound sign (#)	
	• Dollar sign (\$)	
	• Percent sign (%)	
	• Minus sign (-)	
	• Plus sign (+)	
	• Equal sign (=)	
	Open parenthesis sign	
	Close parenthesis sign	
Restrictions	May not have identical consecutive characters	
	May not be the same as your system user name	
	May not be re-used until you have changed the password at least 6 times	
	Must be changed at least every 90 days	

User Access Levels

Your access level is set when the System Administrator creates your user account, and determines which instrument functions you can use. There are three user access levels:

- 1. Operator
- 2. Developer
- 3. Administrator

Table 2 shows the tasks that can be performed at each access level.

Note This document identifies all procedures that require Developer or Administrator access. If a procedure does not specify access level, then any user can run it.

Table 2. User access levels

Menu	Operator	Developer	Administrator
Login	x	X	X
Run	Х	X	X
Self Test	Х	X	X
Sync	х	Х	Х
Tools	х	X	X
About System	Х	X	X
Review Results		X	X
Libraries/Methods	Х	X	X
Acquire Signatures		X	X
System Settings			X
Operational Qualification		X	X
Configure microPHAZIR		X	X
Change Password	х	X	х

Best Practices

Contents

- The Key to a Good Scan on page 21
- Choosing the Proper Adaptor on page 22
- Best Practices Tables on page 23

The Key to a Good Scan

The microPHAZIR analyzer makes diffuse reflection measurements of materials that are placed in contact with the instrument nose. These are usually solids or powders. The material must be reflective enough so that the light level reaching the instrument exceeds a threshold set by the application.

Here are some general measurement guidelines:

- The sample must remain motionless and in contact with the nose of the microPHAZIR analyzer during the measurement.
- Instrument light is required for proper measurement. The microPHAZIR analyzer cannot measure through thick paint, paper, or metals.
- Transparent materials are difficult to measure because they do not reflect sufficient light.
- If you must measure transparent material, use a diffuse reflection reference material such as Fluorilon behind the film.
- Some dark materials, notably those containing carbon-black, do not reflect sufficient light for measurement.
- Small samples can be analyzed by placing them on the center portion of the sample window.

Choosing the Proper Adaptor

Adaptors are rarely used, but when they are needed it is important to select the right one. Choose your adaptor according to the path length requirements of the liquid you are scanning. The microPHAZIR includes the following adaptors:

- Cuvette adaptor for transmission measurements on liquid samples.
- Liquid vial adaptor for transmission measurement on small vials.
- Solids vial adaptor for measuring diffuse reflectance from powder (typically) samples.

Figure 7. microPHAZIR Analyzer with Cuvette Adaptor Attached



All of the adaptors use the same attachment method which is described in "Using Optional Accessory Adaptors" on page 9.

Best Practices Tables

The Best Practices tables on the following pages provide techniques for positioning the focal point for common scanning situations.

Table 3. Best practices for containers

Situation	Recommendation
Thin-walled container	Hold the nose cone tip on the container surface.
1/8 inch (3 mm) or less thick, made of clear or translucent glass or plastic	Tip Containers that feel crushable or squeezable are usually thin walled.
Examples: Standard glass vial and 2ml - 6ml polyethylene bags	

Table 4. Best practices for vials

Situation	Recommendation
Solid sample Powder sample	1. Fill the vial with at least 1 mL of the substance, or to a depth of at least 5 mm (the shaded area shows the minimum amount).
Liquid sample	2. Attach the vial holder.
For liquid samples, pipette the liquid into a glass vial. Add either one QuickDisc OR about ½ cm of QuickSand to the vial. Ensure no air bubbles are trapped. Take spectra through the bottom of the vial. Again collect triplicate scans in one position. Remove vial, then replace and re-collect spectra.	 Insert the vial into the holder. Scan through the bottom of the vial. Note If a powder contains granules of different color and size, manually rotate the vial during the scan so that the light sees each type of granule. Note It is not necessary to solidly pack a vial with a sample solid or paste, but the sample must be in full contact with the side of the vial that the light contacts. Tip Gently tap the vial on a table or counter to compress a powder and eliminate large air pockets.

3 Best Practices Best Practices Tables

Running Methods, Reviewing Results, and Syncing Files

Contents

- Overview on page 25
- Loading Libraries and Methods on page 28
- Running a Method on page 29
- Discover Information for a Fail Result on page 31
- Adding a Note to a Result Screen on page 32
- Reviewing Results on page 32
- Syncing Files on page 33

Overview

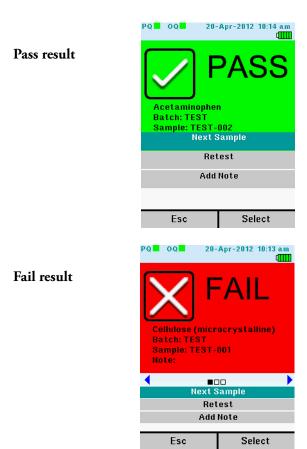
The microPHAZIR analyzer is used primarily to *run a method* on a material sample. A method compares a material's reference spectrum to the spectrum that the instrument generates during a scan. This chapters explains how to run methods. For information on how to create a method, see Chapter 5, "Creating Signatures and Methods".

Depending on the type of method you run, scans results can be:

- Pass/Fail
- Identification
- Quantitative

Pass/Fail scan results

A Pass/Fail scan can have two results. A spectra match displays a Pass result, while no match displays a Fail result.

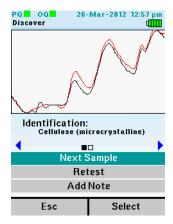


Identification scan results

In an Identification scan, spectral results compare the sample material against library items. The red line spectrum represents the library item and the black line spectrum represents the scanned material.

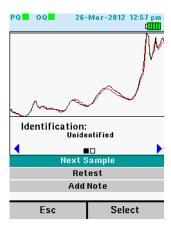
In an Identification result, the sample name is provided

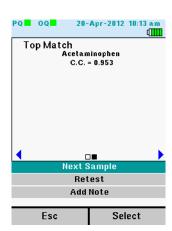
Identification result



When there is no match, the result is unidentified. Press the keypad right arrow to view a Top Match screen.

Unidentified result and Top Match screen





Quantitative scan results

In a quantitative scan, the result displays the percentage of material found in the sample.



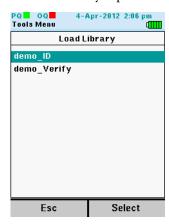


Loading Libraries and Methods

Before you can run a method, you must first load a library (containing methods) into the instrument. The instrument may contain several libraries, but you can only work with one library at a time.

❖ To load libraries and methods

- 1. Login to the microPHAZIR analyzer.
- 2. Select **Tools** > press the Select key.
- 3. Select **Libraries/Methods** > press the Select key.
- 4. Choose a library > press the Select key.



This loads the library (containing methods) into the instrument.

Running a Method

Running a method requires selecting a method, a batch id, and a sample id.

- A method collects sample data and compares the acquired data to a pre-defined reference spectrum.
- A **batch id** lets you group all the method runs for a batch into a single, concatenated report (a spreadsheet). This makes it easier to approve an entire batch. To view the spreadsheet, drag the .txt file into Excel.
- A **sample id** tracks a sample of material to its origin and related test results.

Running methods using a barcode scan

You can scan a barcode to select a method. Using the barcode limits errors and speeds workflow.

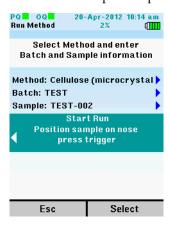
Note You can use the barcode reader whenever the barcode icon is visible in the upper right corner of the Run Method screen.

To run a method using a barcode scan

- 1. From the Main Menu, select **Run**.
- 2. Press the trigger and scan the barcode.

A method displays if the barcode is recognized.

- 3. (Optional) Select a batch id and a sample id.
- 4. Position the sample and press the trigger to **Start Run**.



When analysis completes, a result screen appears.

Running methods manually

You can manually select a method when the barcode option is not available. Use the keyboard to enter a Batch ID and Sample ID.

Note Special characters cannot be used for Sample ID and Batch ID names, and are disabled on the microPHAZIR keypad. Use only alphanumeric characters when creating these files names.

To run a method manually

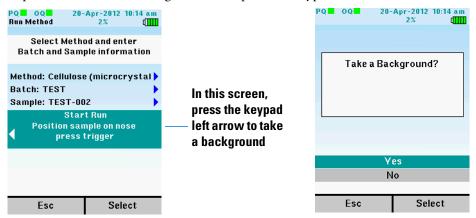
- 1. From the Main Menu, select **Run** > press the Select key.
- 2. Select a method from the list > press the Select key.



3. Select **Batch ID** > press the Select key.

Select a batch ID from the list, or add a new ID.

- 4. (Optional) Select a sample ID from the list, or add a new ID.
- 5. (Optional) To collect a background scan, press the keypad left arrow then select **Yes**.



6. Position the sample and press the trigger to **Start Run**.

When analysis completes, a result screen appears.

Discover Information for a Fail Result

If you get a Fail result, you can Discover the analysis result that the instrument generated. There are two possible analysis results:

- Single positive match
- No match, meaning the result is unidentified.

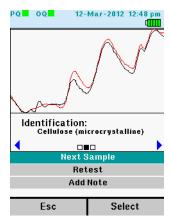
When a positive match is generated, you can view the spectrum.

❖ To discover information for a Fail result

1. From the Fail screen, press the right arrow soft key.



2. The Fail spectrum displays. The red line spectrum represents the library item and the black line spectrum represents the scanned material.



Adding a Note to a Result Screen

You can add a note to a result screen. For example, adding a note to a fail result may help troubleshoot the problem.

❖ To add a note

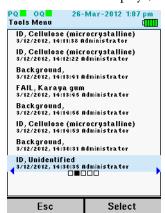
- 1. From the result screen, select **Add Note** > press the Select key.
- 2. Use the keyboard to write a short note. When finished, select **Done**.

Reviewing Results

Every time you run a method or perform a test, the instrument stores the result. When you sync the instrument, results are copied to an archive folder then deleted from the instrument.

❖ To review run results

- 1. In the Main menu, select **Tools** > press the Select key.
- 2. Select **Review Results** > press the Select key.
- 3. The result screen displays, as shown below.



4. To view more details, highlight a result and press the Select key (example below).



Syncing Files

Every task you perform on the microPHAZIR analyzer is recorded in a file. When you Sync the instrument, files are transferred from the instrument to a folder on a network computer. Before Syncing files, some configuration is required (see "Selecting an Archive Destination" on page 53). If a Sync attempt fails, it is noted in the Audit log file.

Note For optimal performance, Thermo Fisher recommends you Sync the analyzer every 200 scans.

Table 5 lists all the available formats for each file type. You can select the report formats in the microPHAZIR Admin tool (see "Formatting Reports" on page 53).

Table 5. Files copied into the archive destination folder

Туре	Available Formats
Runs	PDO, TXT, PDF, and PNG
Self tests	PDO, TXT, PDF, and PNG
Unit certification	PDO, PDF
Batch report	TXT
Sync summary	TXT
Audit log	TXT and PDF

Synchronize the instrument

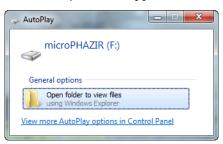
- 1. On your PC, make sure microPHAZIR Admin is running. You can start it by clicking **Start > microPHAZIR Admin**.
- 2. In the microPHAZIR analyzer Main menu, select **Sync** > press the Select key. The instrument shows how many files are available to sync.



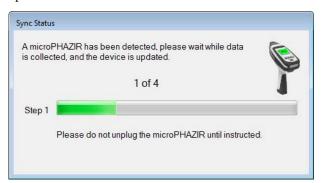
3. Connect the microPHAZIR analyzer to your PC, using the USB cable provided.

4 Running Methods, Reviewing Results, and Syncing Files Syncing Files

4. An AutoPlay window appears, as shown below. Close this window.



5. The Sync process begins. A progress bar on the screen shows the progress of the operation.



- 6. When the sync completes, a confirmation message displays and files are deleted from the instrument. If the sync fails:
 - the files remain on the instrument
 - the failure is recorded in the Audit log file



Creating Signatures and Methods

Contents

- What are Methods and Signatures? on page 35
- Best Practices for Acquiring Signatures on page 36
- Acquiring Signatures on page 37
- Building Libraries on page 39
- Importing Libraries on page 41

What are Methods and Signatures?

The primary use of the microPHAZIR is to "run a method". **Methods** are analytical tasks that identify a sample material. For example, you could run a method to identify fructose.

Methods compare the spectral data collected in a scan to stored reference spectra called **Signatures**. Each method contains a collection of signatures.

Typically, when you run a method the instrument displays a Pass result if the comparison yields a match or a Fail result if the comparison does not match. Two other scan results are described in "Identification scan results" on page 27 and "Quantitative scan results" on page 28.

Best Practices for Acquiring Signatures

Signatures are acquired through a special set of scans. Signatures are the building blocks used to create methods, so extra care is required to take these scans.

Obtaining representative samples for the method

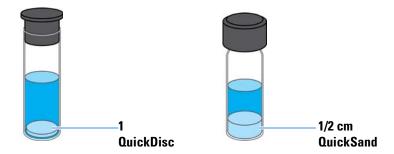
- 1. Obtain realistic samples, meaning samples that are representative of the materials to be identified. No selectivity is implied for materials until the library is built and validated.
- 2. Obtain different batch, lot, and vendor samples that are representative of the library. Different batches, lots and especially vendors may have slightly different specifications for the same material. Ideally, five different batches or lots are required for a library.
- 3. Samples can be measured in either glass vials (glass transparent to NIR), or PE baggies (common thickness of 4 mil). Ensure there is sufficient material to:
 - Fill vial 1/3 to 1/2 full
 - Fill bag to 1/2 inch thickness
- 4. Label all materials with a Method name. If appropriate, include a reference value for PLS quantitative analysis.

Obtaining reference values for quantitative methods

- 1. For quantitative analysis, include the full range of measurement in the library. Note that the limits of detection for quantitative models are 1% or higher, with a working precision of 0.1 for high quality samples.
- 2. Obtain replicate samples for at least 3 points over the measurement range (so there will be 3 points in the measurement range, and each point contain at least 3 replicates).
- 3. For realistic model building, obtain at least 10 reference values over the measurement range. As the range size increases, so should the reference values collected.
- 4. Use reference values from a reliable, authenticated source. The reference values must be reproducible and properly referenced (including validation method, how the reference was obtained, instrumentation, and statistical analysis).
- 5. Collect the spectra and the reference values from the same sample. Collect the spectra first, then use half of the entire sample to obtain the reference value.

Option for collecting methods for liquid samples

- 1. At the minimum, collect triplicate scans in 3 positions. Shake the vial between each positional change. This is sufficient for pure, well-characterized materials common to pharmaceutical samples.
 - If you are using the vial holder and scanning through the side of the vial, rotate the vial through 3 positions and take triplicate scans at each position.
 - If you do not have a vial holder, you can scan through the bottom of the vial. For liquid samples, pipette the liquid into a glass vial. Add either one QuickDisc (Optional Part number 820-00169-01) or ½ cm of QuickSand (Optional Part number 820-00168-01) to the vial.



- To collect spectra through a polyethylene bag, position the microPHAZIR where adequate sample is present, collect triplicate scans in different locations. Make sure you are not collecting through a double thickness of the bag.
- Eliminate any air bubbles. Take spectra through the bottom of the vial. Again collect triplicate scans in one position. Remove vial, then replace and collect spectra again.
- 2. Repeat for the next lot, batch, or vendor.
- 3. Repeat for the next sample.
- 4. For agricultural or food samples, repeat the above protocol 5-10 times. Positioning is important and varies depending on the material. Contact support for more instructions (see "Contacting Us" on page 3).

Acquiring Signatures

To acquire signatures, you perform five scans to produce high quality spectra.

Note Before acquiring signature, make sure to read Best Practices for Acquiring Signatures on page 36.

The procedure below uses the vial holder. However another scanning methods might be more appropriate for your work flow.

To acquire a signature

- 1. Place sample material in a vial. Attach the vial holder to the instrument and insert the vial.
- 2. In the Main menu, select **Tools** > press the Select key. Select **Acquire Signatures** > press the Select key.
- 3. Select **Signature Settings** > press the Select key.



4. Set the number of scans and click **Save**. Minimum is 3 Spectra per Method and 5 for Background and Sample scans.



- 5. Select a method or add a new method
- 6. Provide a **Batch ID** and **Sample ID**.

Note Special characters cannot be used for Sample ID and Batch ID names, and are disabled on the microPHAZIR keypad. Use only alphanumeric characters when creating these files names.

- 7. Select **Continue to Start Run** and press the trigger.
- 8. When **Go** displays, press the trigger to begin scanning.
 - The first scan occurs, and the spectrum appears.
 - Reposition the sample, then take the next scan.
 - Continue until you collect five scans, repositioning the sample between each scan.



9. When the scan results appear, evaluate the quality of the displayed spectrum.

10. Select **Save Current Signature** or **Cancel without Saving** > press the Select key.

Building Libraries

Libraries contain a group of similar methods. For example, a sugar library might contain methods for sucrose, glucose, lactose, maltose, fructose, and galactose.

- You build libraries using the Method Generator. The procedure below describes how to build a simple library, working in 'Easy Mode.'
- After you build a library in Method Generator, use the microPHAZIR Admin tool to import it into a microPHAZIR instrument.
- After importing the library, you must load it to run its methods. For example, after you
 load a sugar library you can run methods for sucrose, glucose, lactose, maltose, fructose,
 or galactose.

❖ To build a library in Method Generator

- 1. Acquire signatures first (see "Acquiring Signatures" on page 37). Signatures are required to build a library.
- 2. Sync the instrument to transfer signatures to an archive folder (see "Synchronize the instrument" on page 33.
- 3. Use the USB cable provided to connect the microPHAZIR instrument to the PC.
- 4. Select **Sync** to copy the signature data file to the archive folder (see "Managing Data" on page 52).
- Open the Method Generator software. From the Windows Start menu select Thermo Scientific Method Generator > Method Generator, or double click the Method Generator desktop icon.

5 Creating Signatures and Methods Building Libraries

- 6. Make sure you are in Easy Mode:
 - In the menu bar, click **Model**.
 - Make sure **Enable ADVANCED Modeling** is disabled.
- 7. Click Import Signatures or Data File.

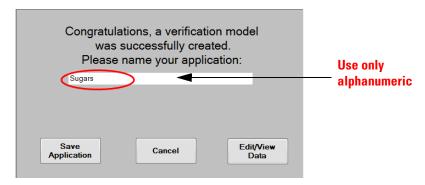


- 8. Select a signature file. An example file name is **BatchCollect_Signatures_9999.PDO**.
- 9. The Method Generator automatically creates an application file. In Method Generator, the term "application" means "library".

Name the application and click **Save Application**.



WARNING Do not use special characters in the application name and its contents. If you do, the microPHAZIR unit will lock up when you import the application. Use only alphanumeric characters.



10. Method Generator tells you where the files were saved. For example:

Application and Project Files have been saved to their respective folders:

\Thermo\Data\Method Generator\Applications\

\Thermo\Data\Method Generator\Projects\

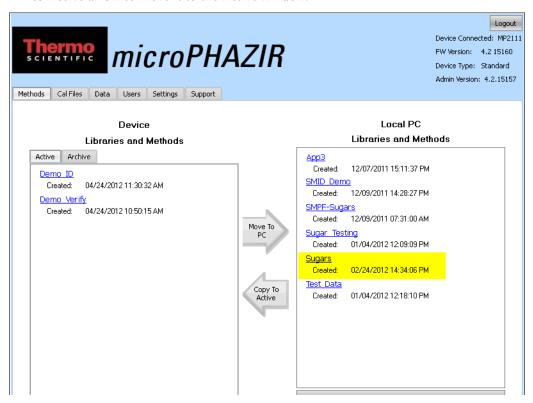
These folders are easily accessed from the 'File' drop down menu

Importing Libraries

Libraries (collections of methods) are created in the Method Generator and automatically saved to on the PC. Before you can run methods in a library, you must import them into the microPHAZIR instrument.

To import libraries into a microPHAZIR

- 1. Open the Admin Tool.
- 2. Select an item from the Local PC window (**Sugars** in the example below). Click the **Copy to Active** arrow to move it to the Active window.



Once the library is in the Active window, it displays in the microPHAZIR instrument.

3. To run the library methods, they must first be loaded into the instrument. See Loading Libraries and Methods on page 28.

5 Creating Signatures and Methods Importing Libraries

Using the microPHAZIR Admin Tool

Contents

- Overview on page 43
- Before Installing microPHAZIR Admin on page 44
- Installing microPHAZIR Admin on page 45
- Who Can Use microPHAZIR Admin on page 45
- Connecting to microPHAZIR Admin on page 45
- Managing Methods on page 47
- Managing Data on page 52
- Managing User Accounts on page 55
- Configuring System Settings on page 58

Overview

You can manage these microPHAZIR configuration settings from the microPHAZIR Admin tool:

- Add or remove Methods and view Signatures
- Manage barcodes, add/edit IDs
- Configure report formats and set an archive destination
- Create user accounts and set user access privileges
- Manage general user settings and instrument certification details
- Import and export the instrument configuration

Before Installing microPHAZIR Admin

Before installing microPHAZIR Admin tool on your computer, do the following things:

Make sure your computer is running Window 7 or 8

Install a PDF reader

Install Adobe Reader or another PDF reader on your computer. PDF readers are available for free download from the Web.

❖ Install .NET Framework 3.5 or later

 Open a web browser and go to the following site: http://msdn.microsoft.com/en-us/netframework/cc378097

2. Download and install .NET Framework.

Set Archive folder permissions

You need PC Admin privileges to set Archive folder permissions. This example uses the default Archive folder location (C:\Thermo\Data\ARCHIVE). If a different Archive folder is used, set the same permissions on that folder.

- 1. Create a C:\Thermo\Data\ARCHIVE folder.
- 2. Right-click ARCHIVE and select Properties.
- 3. Click the Security tab, then click **Edit**.
- 4. Set Delete permissions to **Deny**, as shown below:



5. Click **Apply**, then click **OK**.

Installing microPHAZIR Admin

You must install the client application software to run the microPHAZIR Admin tool.

❖ To install the client application software

- 1. Insert the microPHAZIR software CD into your computer CD-ROM drive.
- Follow the installation Wizard instructions to install the software.
 When you finish, a microPHAZIR Admin client will display on your desktop.



Who Can Use microPHAZIR Admin

Access to microPHAZIR Admin is based on user accounts.

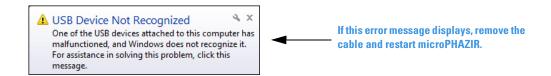
- Administrators: No restrictions, full access to all microPHAZIR Admin features
- Developers: Access to Methods tabs only, no access to Archives, Settings, and Users tabs.
- Operators: No access to any microPHAZIR Admin features

Connecting to microPHAZIR Admin

The microPHAZIR Admin tool connects directly to the microPHAZIR via a USB cable. The microPHAZIR Admin executable file must be on your PC for the connection to work. See "Installing microPHAZIR Admin."



WARNING Do not start up microPHAZIR with the USB sync cable attached to PC, otherwise Windows fails to recognize the USB driver. If this occurs, you will see the error message below.



❖ To connect to the microPHAZIR Admin tool

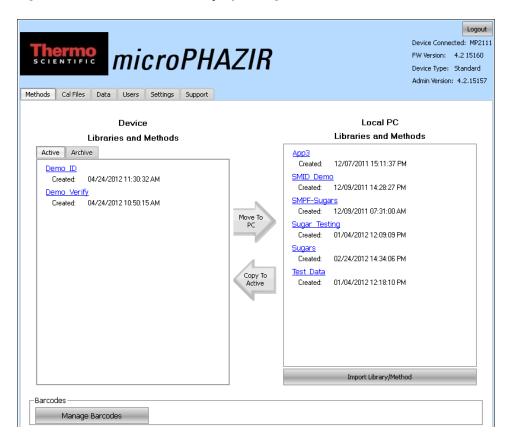
- 1. On your PC, make sure microPHAZIR Admin is running. You can start it by clicking **Start** > **microPHAZIR Admin**.
- 2. From the microPHAZIR analyzer main menu, select **Tools** > **Configure microPHAZIR**.

- 3. Choose an option to connect to the microPHAZIR Admin tool:
 - **Configure with Libraries** use this option to work with Methods . It can take several minutes to connect, depending on the number of library items.
 - **Configure without Libraries** use this option to configure user accounts, general settings, or archive settings. The connection is faster because libraries are not loaded.
- 4. Connect the microPHAZIR instrument to your PC, using the USB cable provided.

After you login, microPHAZIR Admin displays the Methods page (Figure 8). A quick overview of each page's functionality is described below:

- Methods: add and remove libraries and methods, view methods and signatures, manage IDs and barcodes
- Cal Files: this tab is disabled. Cal Files are used only in the microPHAZIR AG unit.
- Data: setup archive folder, format reports, import and export configuration files
- Users: add, edit, and delete user accounts
- Settings: configure login settings, manage PQ and OQ certification
- **Support**: lists registration & device information

Figure 8. A methods screen displays at login

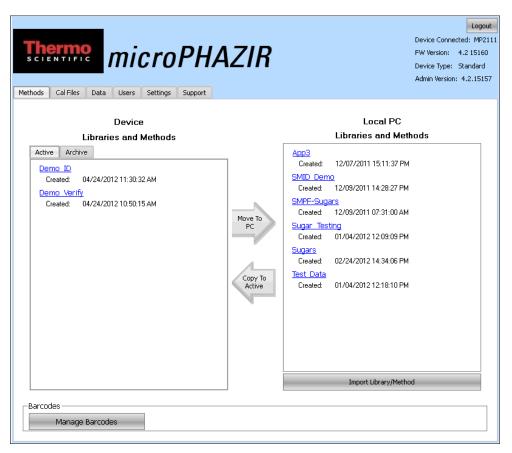


Managing Methods

From the Methods tab (see Figure 9), you can add Libraries and Methods to the instrument (Active), or remove them (Archived). Libraries contain a group of similar methods. For example, a sugar library might contain methods for sucrose, glucose, lactose, maltose, fructose, and galactose. For each method you can view signatures and their associated spectra.

From the Methods tab, you can also manage barcodes.

Figure 9. Methods tab



Adding libraries and methods to the instrument

- **❖** To add libraries and methods to the instrument
- 1. Login to microPHAZIR Admin. The **Methods** tab displays by default.
- 2. From the Archived Libraries and Methods window, select the items you want to add.
- Click the directional arrow to move items to the Active Libraries and Methods window.
 The libraries and methods are immediately available in the instrument.

Removing libraries and methods from the instrument

Removing libraries and methods from the instrument moves them to the archive, but it does not delete them. To delete libraries and methods, you must delete them from your local PC.

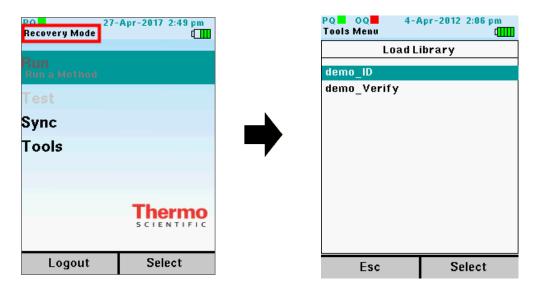
❖ To remove libraries and methods from the instrument

- 1. Login to microPHAZIR Admin. The **Methods** tab displays by default.
- 2. From the **Active Libraries and Methods** window, select the items you want to remove.
- 3. Click the directional arrow to move items to the **Archived Libraries and Methods** window.

The libraries and methods are immediately removed from the instrument.

Troubleshooting Tip If you accidentally remove the active library from the instrument, the analyzer goes into "Recovery Mode".

To exit Recovery Mode go to **Tools > Libraries/Methods** and load a new library.



If you need more help loading a new library, see "Loading Libraries and Methods" on page 28.

Editing libraries and methods

To edit libraries and methods, you must use the Method Generator software.

Note In the Method Generator software, libraries are called "applications".

To edit methods

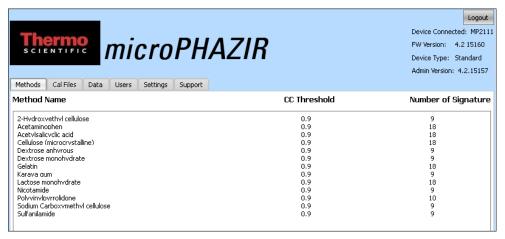
- Open the Method Generator application.
- From the menu bar, select **Model** > **Enable ADVANCED Modeling**.
- Refer to the Method Generator User Guide for details on editing applications.

Viewing method details

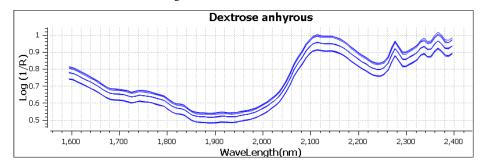
From the Methods tab you can view details for libraries and methods.

To view methods and signatures

- 1. Login to microPHAZIR Admin. The **Methods** tab displays by default.
- 2. Click a library (blue link) to view its methods. The CC (Correlation Coefficient) Threshold value is assigned in the Method Generator.



3. Click a method to view its signature scans.



4. Click **Close** to return to the top level methods view.

Editing IDs

Editing IDs in the Admin tool is much easier than using the microPHAZIR instrument keyboard. From the Admin tool you can add or delete individual IDs, and import or export CSV files containing multiple IDs.

Note Keyboard special characters are disabled when you create ID names. Use only alphanumeric characters when naming these files.

❖ To edit IDs

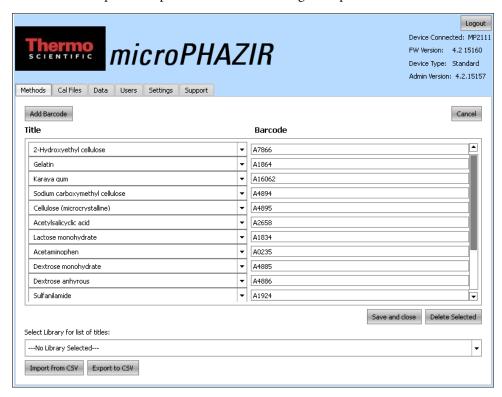
- 1. From the **Methods** tab, click on a library.
- 2. Select an item from the Edit IDs drop down list.
- 3. Click **Edit** and make your changes.



4. When you finish, click **Save and Close**.

Managing barcodes

Barcode speed the scanning process. From the Methods tab you can add or delete individual barcodes, and import or export CSV files containing multiple barcodes.



❖ To add barcodes

- 1. Login to microPHAZIR Admin. The Methods tab displays by default.
- 2. Click Manage Barcodes.
- 3. Click Add Barcode.
- 4. Select a method title from the drop down list or enter a new title, then enter a barcode.
- 5. When you finish adding barcodes, click **Save and Close**.

To delete barcodes

- 1. Login to microPHAZIR Admin. The **Methods** tab displays by default.
- 2. Click Manage Barcodes.
- 3. Select barcodes for deletion, then click **Delete Selected**.
- 4. When you finish deleting barcodes, click **Save and Close**.

❖ To import barcodes

- 1. Login to microPHAZIR Admin. The **Methods** tab displays by default.
- 2. Click Manage Barcodes.
- 3. Click **Import from CSV** and browse to find the file.
- 4. When you double-click the CSV file, the bar codes import immediately.
- 5. Click Save and Close.

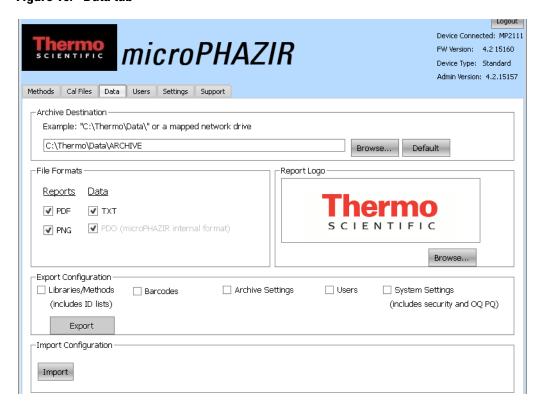
❖ To export barcodes

- 1. Login to microPHAZIR Admin. The **Methods** tab displays by default.
- 2. Click Manage Barcodes.
- 3. Click **Export to CSV**, browse to a folder location and click **Save**.
- 4. Click Save and Close.

Managing Data

From the Data tab (Figure 10), you can configure an archive destination, select report formats and report logos, and transfer microPHAZIR analyzer configuration files.

Figure 10. Data tab



Selecting an Archive Destination

From microPHAZIR Admin, you designate a sync archive destination or accept a default destination.

Note The default destination is C:\Thermo\Data\ARCHIVE

❖ To select a sync archive destination

1. Connect to microPHAZIR Admin, then click the **Data** tab.



- 2. In the **Archive Destination** field, designate a directory using either method below. :
 - Use the default destination, which is C:\Thermo\Data\ARCHIVE\
 - Use a mapped network drive (first make sure the network drive is MAPPED to the local PC, so you can BROWSE to the drive).

Formatting Reports

All the work done using microPHAZIR is captured in reports. Reports are sent to the archive destination when you sync the instrument. You can select report formats and elect to insert a logo.

To format reports

- 1. Connect to microPHAZIR Admin, then click the **Archives** tab.
- 2. In the **Archived Report Formats** field, select the report types you want generated.



3. (Optional) Attach a Report Logo to the report. This is limited to reports in PDF or PNG format.

Exporting Configuration Files

You can export a configuration file and export it to other microPHAZIR analyzers or save it as a backup for your instrument. Configuration files include the following settings:

- Libraries/Methods
- Barcodes
- Archive Settings
- User Settings
- System Settings

You can export all configuration settings or individual settings. Configuration files do not include details specific to individual microPHAZIR analyzers, such as serial number or calibration parameters.

To export a configuration file

- 1. Connect to microPHAZIR Admin, then click the **Data** tab.
- 2. Click check boxes to select the configuration settings, then click **Export**.



3. Select a location, enter a file name and click **Save**. The configuration file is saved in **.mpt** format.

Importing Configuration files

Use this procedure to import a configuration file into your microPHAZIR analyzer. You may use this to restore settings from a backup, or to share settings among multiple instruments.

Note Importing a configuration file overwrites all the saved information on your instrument.

❖ To import a configuration file

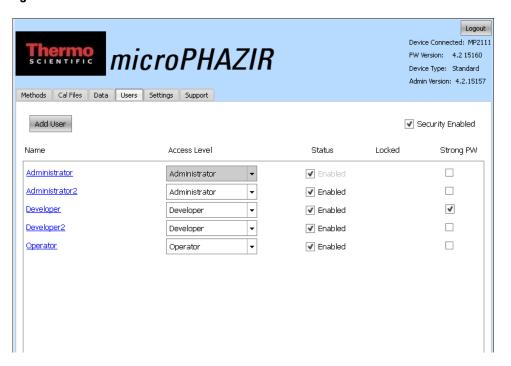
- 1. Connect to microPHAZIR Admin, then click the **Data** tab.
- 2. Click **Import**, and locate the configuration (.mpt) file.
- 3. Select the configuration file and click **Open**.

The imported configuration is available for use.

Managing User Accounts

From the Users tab you can add, edit, and delete users accounts. The tab lists user names, access level and status, and states whether the account is locked.

Figure 11. Users tab

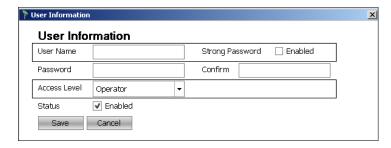


Adding, Editing, or Deleting User Accounts

Only Administrators can configure a user account.

❖ To add a new user

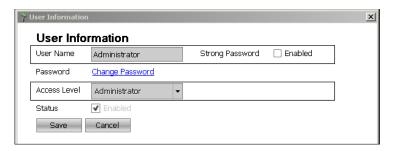
- 1. Login to microPHAZIR Admin, then click the Users tab.
- 2. Click the Add User link.
- 3. Fill in each field, then click **Save**.



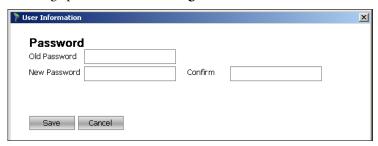
For information on the fields, see Table 6.

❖ To edit a user account

- 1. Login to microPHAZIR Admin, then click the Users tab.
- 2. Click the user name link to edit it. For information on the fields, see Table 6.



3. To change password, click Change Password.



4. After making changes, click Save.

❖ To delete a user

- 1. Login to microPHAZIR Admin, then click the Users tab.
- 2. For each user account you want to delete, click the **Selected** check box.
- 3. Click **Delete Selected**.

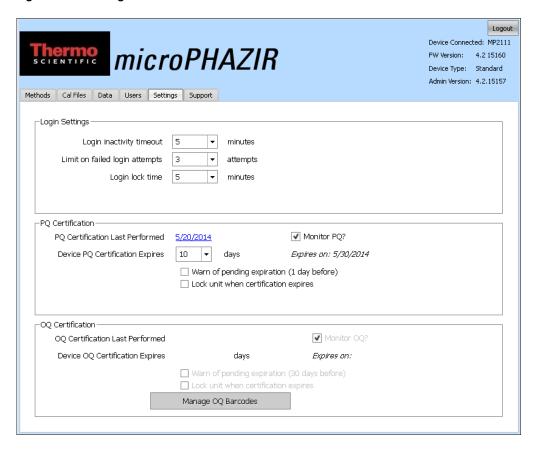
Table 6. User information fields

Field	Description
User Name	Used to access both the microPHAZIR analyzer and microPHAZIR Admin. User names cannot be blank or exceed 24 characters. User names can be composed of letters or numbers and are case-sensitive.
Password	Used to access the microPHAZIR analyzer.
	The requirements are 1-15 characters which can include letters, numbers, spaces, and the following characters: !@#\$%^+=()-"
	If you want to use strong passwords, follow the guidelines in Table 1 on page 19.
Access Level	Includes Operator, Developer, and Administrator. For information on the privileges assigned to the access levels, see Table 2 on page 20.
Strong Password?	Enables or disables enforcement of strong password guidelines, described in Table 1 on page 19.
Status	Enables or disables user access to the microPHAZIR analyzer and microPHAZIR Admin. Disabled accounts do not appear in the microPHAZIR analyzer login list, but they are viewable in microPHAZIR Admin.
Locked	Used to unlock a locked user account. For example, an account may be locked because the user exceeded their allowable number of failed login attempts.

Configuring System Settings

From the Settings tab (Figure 12) you configure instrument settings that apply to all users, regardless of their access level.

Figure 12. Settings tab



Configuring Login Settings

Login settings apply to login actions on the microPHAZIR analyzer.

To configure login settings

1. Connect to microPHAZIR Admin, then click the **Settings** tab.

- 2. In the **Login Settings** fields, select values for the following:
 - Login inactivity timeout: minutes of inactivity allowed before the user is logged out.
 - Limit on failed login attempts: number of times a user may consecutively fail to login. When this number is exceeded the user account is locked. Can be unlocked by an administrator.
 - **Login lock time**: number of minutes a user is locked out before the system lets them back in.



3. The changes are immediately applied as you select values.

Configuring PQ Certification

The performance qualification (PQ) certification verifies that the microPHAZIR analyzer is operating according to its factory settings.

From microPHAZIR Admin, you can set a certification expiration date, a user notification alert, and set the instrument to lock when certification expires.

Note When the certificate expires, you cannot run methods on the instrument. All other functions work. An administrator can clear the lock by deleting the expiration date from microPHAZIR Admin. However, audit logs will show that the instrument is not certified.

❖ To configure PQ certification

- 1. Connect to microPHAZIR Admin, then click the **Settings** tab.
- 2. In the PQ Certification field:
 - · Set the number of days until certification expires
 - Enable or disable all check box items



3. The changes are immediately applied as you select values.

Configuring 00 Certification

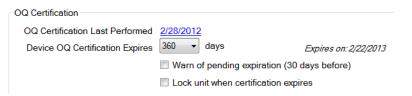
The operational qualification (OQ) is typically an annual certification test, which is a Good Manufacturing Practices (GMP) requirement. Following GMP guidelines, the test requires you to scan five standards provided by Thermo Fisher Scientific.

From microPHAZIR Admin, you can set a certification expiration date, a user notification alert, and set the instrument to lock when certification expires.

Note When the certificate expires, you cannot run methods on the instrument. All other functions work. An administrator can clear the lock by deleting the expiration date from microPHAZIR Admin. However, audit logs will show that the instrument is not certified.

❖ To configure 00 certification

- 1. Connect to microPHAZIR Admin, then click the Settings tab.
- 2. In the OQ Certification field:
 - Set the number of days until certification expires
 - Enable or disable warning of pending expiration
 - Enable or disable locking the instrument when certification expires



- 3. The changes are immediately applied as you select values.
- 4. (Optional) Click Manage OQ Barcodes to change barcode values.



5. After making your changes, click **Save and Close**.

Maintaining Your Unit

Contents

- Running a Self Test on page 61
- Rebooting the Unit on page 63
- Cleaning and Decontaminating the Unit on page 63
- Replacing the Light Bulb on page 63
- Obtaining Replacement Parts on page 65
- Getting Help with Problem Results on page 65
- Creating a Diagnostics File on page 66
- Returning the Unit for Service on page 66
- Running the Calibrate Reference Test on page 67
- Running the Operational Qualification Test on page 68
- Viewing the Serial Number and Software Version on page 70

Running a Self Test

The self test (or performance qualification test) verifies that the microPHAZIR analyzer operates according to its factory settings. Run a self test at least daily to verify that the instrument is operating properly. During the self test, the instrument scans an internal reference material.

The self test has two possible results:

• A **Pass result** means that the instrument correctly identified the chemical makeup of the test material. This result indicates that the instrument is functioning to specifications.



• A Fail result indicates a problem.



Tip At a minimum, you should perform a self test to start and end every work shift. Depending on your department's standard operating procedure, you may elect to conduct the test more frequently than this.

❖ To run a self test

- 1. In the Main menu, select **Self Test** > press the Select key.
- 2. Press the trigger to begin the self test. The instrument takes 6 consecutive scans, then calculates the test data.
- 3. If you get a Pass result, press the Escape key to return to the Main menu. If you get a Fail result, repeat the self test. If you obtain another Fail result, contact Thermo Fisher Scientific Customer Support. See "Contacting Us" on page 3.

Rebooting the Unit

If the instrument becomes unresponsive, reboot it by turning it off, then on again. If the instrument fails to reboot, contact Customer Support. See "Contacting Us" on page 3.

Cleaning and Decontaminating the Unit

To remove nonhazardous contaminants from the instrument and the attachments, wipe them with a soft cloth moistened with water, isopropyl alcohol, or a 10% solution of bleach (sodium hypochloride).

If the instrument is contaminated with potentially hazardous substances, follow your organization's decontamination guidelines.

Before decontaminating the instrument:

- Press the Power key to shut down the instrument.
- Make sure the battery access door is closed, and the USB cover is shut tight.

Replacing the Light Bulb

The microPHAZIR tungsten light bulb will need to be replaced from time to time. A spare bulb kit is included when the analyzer is purchased. Additional bulbs can be obtained from Thermo Scientific.

❖ To change the bulb

1. With the microPHAZIR analyzer turned off, remove the two screws holding the nose cover to the instrument.



7 Maintaining Your Unit Replacing the Light Bulb

2. Remove the nose cover.



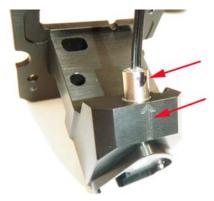
3. Locate the setscrew securing the light bulb in place. Loosen this setscrew with the Allen key provided and extract the bulb. The connecting wires should come out with the bulb to reveal a connector.



4. Disconnect the connector by squeezing the release tab and remove the bulb being careful not to touch or damage the other components in the nose.



5. Insert a new bulb into the socket as far as it will go. Orient the mark on the light bulb with the arrow on the mount and secure it by tightening the set screw.



- 6. Attach the wire connector on the bulb to the plug connector on the microPHAZIR.
- 7. Attach the nose cover using the two screws.
- 8. Power on the microPHAZIR and run the following verification tests:
 - Run a Calibrate Reference test (see "Running the Calibrate Reference Test" on page 67).
 - Run a Performance Qualification test (see "Running a Self Test" on page 61).
 - Run one of the methods (see "Running a Method" on page 29).

Obtaining Replacement Parts

The microPHAZIR analyzer is designed for use in an industrial environment. If needed, you can obtain the following replacement parts from Customer Service:

- 7.2V Li-Ion smart charger (DC Output 8.4V 1.0A) Part #256-00284-01
- Spare Li-Ion battery Part #256-00284-01
- Replacement tungsten bulb Part #580-02331-01
- Documentation CD or hard copy User Guide Part #110-00026-03
- USB cable Part #400-02341-01

Getting Help with Problem Results

For help with method validation, method robustness, and method development or results, telephone Customer Support. See "Contacting Us" on page 3. A customer support representative will discuss the problem with you and help you create and email a file containing scan data, instrument calibration data, and the system log.

❖ To export a problem result

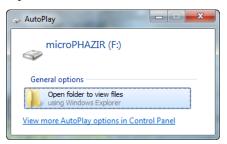
- 1. In the microPHAZIR analyzer Main menu, select **Sync** > press the Select key.
- 2. Connect the microPHAZIR to your computer, using the USB cable provided.
- 3. Once connected, locate the drive with the name MP### (#### is the serial number).
 - The root directory contains collected data and model results in encrypted .PDO files.
 - All file names contain the application name followed by _Results
- 4. Locate the data file for the application you are having difficulty with.
- 5. Send the file to Customer Support. See "Contacting Us" on page 3.

Creating a Diagnostics File

Contact Customer Support before creating a diagnostic file. See "Contacting Us" on page 3. If you have a serious problem with your instrument, Customer Support will ask you to create a diagnostics file and email it them.

To create a diagnostics file

- In the Main menu, select Tools > Configure microPHAZIR > Get Diagnostics press the Select key.
- 2. The instrument creates a file named **Diagnostics.tar.gz**.
- 3. Connect the microPHAZIR to your computer, using the USB cable provided.
- 4. Open the microPHAZIR device folder and copy **Diagnostics.tar.gz** to your desktop.



5. Attach Diagnostics.tar.gz to an email, and send it to support@chemid.thermofisher.com.

Returning the Unit for Service

Before returning the instrument, contact Customer Support or your local distributor and request a return material authorization (RMA) number.

Note Packages that are not identified with an RMA number will be returned unopened.

To return an instrument

- 1. Clean the instrument and decontaminate it if necessary (see "Cleaning and Decontaminating the Unit" on page 63). Both safety and common carrier requirements require all returned instruments to be clean and decontaminated.
- 2. Package the instrument securely and write your RMA number on the outside of the package.
- 3. Mail the package to Customer Support.

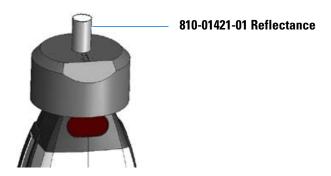
Running the Calibrate Reference Test

Run this test to correct for any slight alignment changes. For example:

- After the plastic nose cover is removed to change the light bulb
- Any time the instrument is exposed to large thermal excursions or mechanical vibrations (airplane transportation for example)
- Any time the instrument is not used for long periods of time or loses accuracy

❖ To run the calibrate reference test

- 1. In the Main menu, select **Tools** > press the Select key.
- 2. Select **Configure microPHAZIR** > press the Select key.
- 3. Select **Calibrate Reference** > press the Select key.
- 4. Place the reference holder on the microPHAZIR and insert the 810-01421-01 reflectance standard.



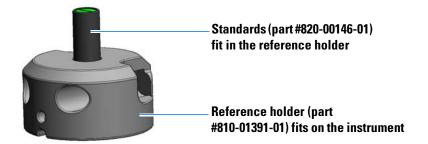
- 5. Press the trigger or the Select key to begin calibration.
- 6. When the calibration completes, a success message displays. Select **OK** to continue.

Running the Operational Qualification Test

Annual certification is a Good Manufacturing Practices (GMP) requirement. Following GMP guidelines, the test requires you to scan five standards provided by Thermo Fisher Scientific.

After you run the test, send the file to Customer Support. If the results meet the standard for your analyzer, Customer Support sends you an annual certification for the instrument.

Use the reference holder (shown below) to hold standards in place during testing.



❖ To perform the operational qualification test

- 1. In the Main menu, select **Tools** > press the Select key.
- 2. Select **Operation Qualification** > press the Select key.
- 3. Press the trigger to begin testing.
- 4. Press the trigger and scan the barcode for the A standard.
- 5. Place the A standard in the reference holder and press the trigger to continue.

When the scan completes, the A standard box turns green



6. Continue testing each additional standard, first scanning the barcode and then performing a scan. All the boxes should be marked green.



7. After scanning all 5 standards, the test results are displayed. A Pass result is shown below.



If you get a Fail result, repeat the test. If you receive a second Fail result, contact Customer Support.

- 8. Synchronize data immediately and retrieve the annual certification file (see "Synchronize the instrument" on page 33).
- 9. Send the certification test results file to Customer Support.

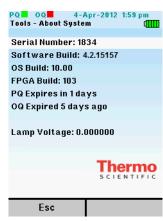
Viewing the Serial Number and Software Version

You can view the serial number and software version on your instrument. You will need the software version before you upgrade.

To locate the serial number and software version number

- 1. In the Main menu, select **Tools** > press the Select key.
- 2. Select **About System >** press the Select key.

The serial number and software version are listed at the top of the screen.



Using the Method Generator

Contents

- Installing and Registering Method Generator on page 71
- Using Secure Mode and Audit Logs on page 72
- Login and User Privileges on page 73
- Collecting Data to Create Application Scripts on page 74
- Evaluating Spectra in Method Generator on page 74

The microPHAZIR analyzer is used primarily to run methods on material samples. A method is an application script that tells microPHAZIR how to take and analyze spectra for a specific material. These application scripts are created in the Method Generator.

Installing and Registering Method Generator

After installing Method Generator, you must also install Microsoft .NET Framework 2.0 (or later). The first time you run Method Generator, it will notify you that it is not registered. Registration is required for the program to fully function (for example, you cannot build Applications until you register).

Install Method Generator

- 1. Insert the Method Generator software CD into your computer CD-ROM drive, or download the software from Thermo Fisher Scientific Customer support.
- 2. Double-click **setup.exe**.
- 3. Follow the installation Wizard instructions to install the software.

Install .NET Framework 2.0 or later

- 1. Open a web browser.
- 2. Go to the following site:

http://www.microsoft.com/download/en/details.aspx?id=16614

3. Download and install .NET Framework.

* Register Method Generator

- 1. Open the Method Generator program.
- 2. Click Help on the menu bar.
- 3. Click Register.



4. Enter the 4-digit serial number of the microPHAZIR that will be used with this software. If the software will be used in "Secure Mode" then append the letters "RX" to the serial number.

Using Secure Mode and Audit Logs

Secure Mode ensures that Method Generator follows 21 CFR guidelines. When Secure Mode is enabled, Method Generator requires users to login and Audit Logs are kept for most operations.

1. If a user registers with "RX" appended to the serial number (see step 4 above), the following screen displays:



2. Click **OK**. Select a folder (on your PC or a network computer) to save audit logs in, then click **OK** again.



3. The program terminates and must be restarted.

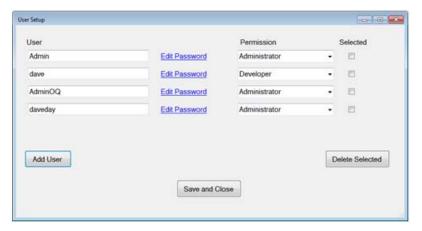


Login and User Privileges

- 1. After the program restarts (see step 3 above) a Login screen displays.
- 2. Enter **Admin** in the User Name field. The Password field is initially empty, so click the button marked below.



3. The User Setup dialog displays.



- 4. Enter a password for the Admin account.
- 5. Continue adding user accounts as needed. **Administrator** and **Developer** are the only account types available.

Collecting Data to Create Application Scripts

To create application scripts, you first need to collect stored reference spectra called signatures.

- The microPHAZIR analyzer collects signatures.
- The Admin tool copies signatures from the microPHAZIR to a network folder.
- Method generator uses signatures to create application scripts.

Note Use only alphanumeric characters when you name applications or create file contents. If application names or file contents contain special character, microPHAZIR will lock up when you import them.

Evaluating Spectra in Method Generator

Performing initial evaluation

- 1. Load the collected data into the Method Generator tool.
- 2. Delete any data showing absorbances (y-axis) past 3.
- 3. Delete any noisy spectra, especially at high absorbance.
- 4. Highlight each group to make sure that all spectra look similar in the same group. Delete any obvious single outliers. The best scenario is when the triplicate scans are right on top of each other, with little difference between positional scans. However, as long as the positional replicates appear similar and are close together, this is adequate. If one position is obviously off from the others, keep it, but watch to see if it affects the final results.
- 5. Delete spectra if an obvious mistake was made. However, do not delete spectra that is merely suspicious. Deviations from the norm could be due to actual inherent sample differences, and need to become part of the model
- 6. If you have reference values, input them at this time using the Edit Y-value option.
- 7. Save the final edited data with a unique name.

Generating Methods

- 1. Proceed through the standard pre-processing options, and then evaluate the model using Spectral Match.
- 2. Look for adequate separation between GroupIDs. There should be a gap between the colors associated with one group and the next closest color of the nearest group.
- 3. To correct for effects of the polyethylene bag, truncate the wavelength range to (1810-2210nm).
- 4. Save the model if it appears to be adequate.

5. To test the model:

- a. Load the data and either the pbe (encoded) or txt (unencoded) files onto the microPHAZIR
- b. Make sure the model correctly identifies samples that were present in the library building sample set.
- c. Make sure the model correctly identifies samples that were not part of the library building set but are the same materials.
- d. If these are not identified correctly, add them to the library and rebuild the model.

A Using the Method Generator Evaluating Spectra in Method Generator

Limited Warranty

Seller warrants that the Products will operate or perform substantially in conformance with Seller's published specifications and be free from defects in material and workmanship, when subjected to normal, proper and intended usage by properly trained personnel, for the period of time set forth in the product documentation, published specifications or package inserts. If a period of time is not specified in Seller's product documentation, published specifications or package inserts, the warranty period shall be one (1) year from the date of shipment to Buyer for equipment and ninety (90) days for all other products (the "Warranty Period"). Seller agrees during the Warranty Period, to repair or replace, at Seller's option, defective Products so as to cause the same to operate in substantial conformance with said published specifications; provided that Buyer shall (a) promptly notify Seller in writing upon the discovery of any defect, which notice shall include the product model and serial number (if applicable) and details of the warranty claim; and (b) after Seller's review, Seller will provide Buyer with service data and/or a Return Material Authorization ("RMA"), which may include biohazard decontamination procedures and other product-specific handling instructions, then, if applicable, Buyer may return the defective Products to Seller with all costs prepaid by Buyer. Replacement parts may be new or refurbished, at the election of Seller. All replaced parts shall become the property of Seller. Shipment to Buyer of repaired or replacement Products shall be made in accordance with the Delivery provisions of the Seller's Terms and Conditions of Sale. Consumables are expressly excluded from this warranty.

Notwithstanding the foregoing, Products supplied by Seller that are obtained by Seller from an original manufacturer or third party supplier are not warranted by Seller, but Seller agrees to assign to Buyer any warranty rights in such Product that Seller may have from the original manufacturer or third party supplier, to the extent such assignment is allowed by such original manufacturer or third party supplier.

In no event shall Seller have any obligation to make repairs, replacements or corrections required, in whole or in part, as the result of (i) normal wear and tear, (ii) accident, disaster or event of force majeure, (iii) misuse, fault or negligence of or by Buyer, (iv) use of the Products in a manner for which they were not designed, (v) causes external to the Products such as, but not limited to, power failure or electrical power surges, (vi) improper storage and handling of the Products or (vii) use of the Products in combination with equipment or software not supplied by Seller. If Seller determines that Products for which Buyer has requested warranty services are not covered by the warranty hereunder, Buyer shall pay or reimburse Seller for all costs of investigating and responding to such request at Seller's then prevailing time and materials rates. If Seller provides repair services or replacement parts not covered by this warranty, Buyer shall pay Seller therefor at Seller's then prevailing time and materials rates.

B Limited Warranty

ANY INSTALLATION, MAINTENANCE, REPAIR, SERVICE, RELOCATION OR ALTERATION TO OR OF, OR OTHER TAMPERING WITH, THE PRODUCTS PERFORMED BY ANY PERSON OR ENTITY OTHER THAN SELLER WITHOUT SELLER'S PRIOR WRITTEN APPROVAL, OR ANY USE OF REPLACEMENT PARTS NOT SUPPLIED BY SELLER, SHALL IMMEDIATELY VOID AND CANCEL ALL WARRANTIES WITH RESPECT TO THE AFFECTED PRODUCTS.

THE OBLIGATIONS CREATED BY THIS WARRANTY STATEMENT TO REPAIR OR REPLACE A DEFECTIVE PRODUCT SHALL BE THE SOLE REMEDY OF BUYER IN THE EVENT OF A DEFECTIVE PRODUCT. EXCEPT AS EXPRESSLY PROVIDED IN THIS WARRANTY STATEMENT, SELLER DISCLAIMS ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, ORAL OR WRITTEN, WITH RESPECT TO THE PRODUCTS, INCLUDING WITHOUT LIMITATION ALL IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE. SELLER DOES NOT WARRANT THAT THE PRODUCTS ARE ERROR-FREE OR WILL ACCOMPLISH ANY PARTICULAR RESULT.

Regulatory Statements

FCC and Industry Canada Statements

This equipment has been tested and found to comply with the limits for a Class A digital instrument, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

The instrument is not intended to be used in a hazardous location. The battery pack should be charged only with a suitably certified or approved battery charger.

This Class A digital apparatus meets all requirements of the Canadian Interference-Causing Equipment Regulations.

Cet appareil numérique de la Classe A respecte toutes les exigences du Règlement sur le matériel brouilleur du Canada.



CAUTION This is a Class A product. In a domestic environment this product may cause radio interference, in which case the user may be required to take adequate measures.

Export Regulation Statements



CAUTION The technical information contained with this document is subject to the Export Administration Regulations. Export of this technical information to foreign persons or foreign companies, within or outside the United States, may require prior written authorization by the U.S. Department of Commerce, Bureau of Industry and Security. Contact Thermo Scientific, Inc. prior to such a transfer.

C Regulatory Statements Statements

Statements

This equipment is in conformity with the provisions of the following EC Directives:

- EU Low-Voltage Directive (LVD)
- EU Electromagnetic Compatibility (EMC) Directive
- EU Waste of Electrical and Electronic Equipment (WEEE) Directive
- EU Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment (RoHS)

European WEEE

WEEE Compliance

This product is required to comply with the European Union's Waste Electrical & Electronic Equipment (WEEE) and is marked with the following symbol:



This product shall be returned to Thermo Fisher Scientific or sent to a licensed disposal facility at the end of its useful life. Do not dispose in normal waste stream.

WEEE Konformität

Dieses Produkt muss der Richtlinie der Elektro- und Elektronik-Altgeräte der Europäischen Union (WEEE) entsprechen und ist mit folgendem Symbol gekennzeichnet:



Dieses Produkt muss am Ende seiner Nutzungsdauer an Thermo Fisher Scientific zurückgegeben, oder an eine lizenzierte Entsorgungseinrichtung gesendet werden. Nicht im normalen Abfall entsorgen.

Conformité DEEE

Ce produit doit être conforme aux normes pour la gestion des déchets d'équipements électriques et électroniques de l'Union européenne (DEEE) et porte le symbole suivant:



Ce produit doit être renvoyé à Thermo Fisher Scientific ou envoyé à un centre d'élimination agréé à la fin de sa durée de vie. Ne pas jeter dans un flux de déchets normal.

C Regulatory Statements European WEEE

