

INSTRUCTION MANUAL FOR THE FLUXERGY ANALYZER SYSTEM

REF 5506-CE

For *In Vitro* Diagnostic Use

For Professional Use Only





DISCLAIMER

* Refer to your respective Instructions for Use (IFU) for product-specific instructions.

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MAINTAINING A SAFE WORKSPACE

Use of Personal Protective Equipment (PPE)

Follow your lab's PPE guidelines. The use of gloves, eye protection, and proper attire are recommended with use of Fluxergy Analyzer and products.

Disinfection of Laboratory Workspace

The regular disinfection of your laboratory workspace is recommended to reduce risk of contamination. The exterior of the Fluxergy Analyzer can be gently wiped down with 70% isopropyl alcohol.

Biohazard Waste Disposal

When testing biological samples, it is important to consider the proper disposal of samples. You are responsible for following the proper biosecurity protocols in your jurisdiction. Use appropriate biohazard refuse containers to dispose all used test components.

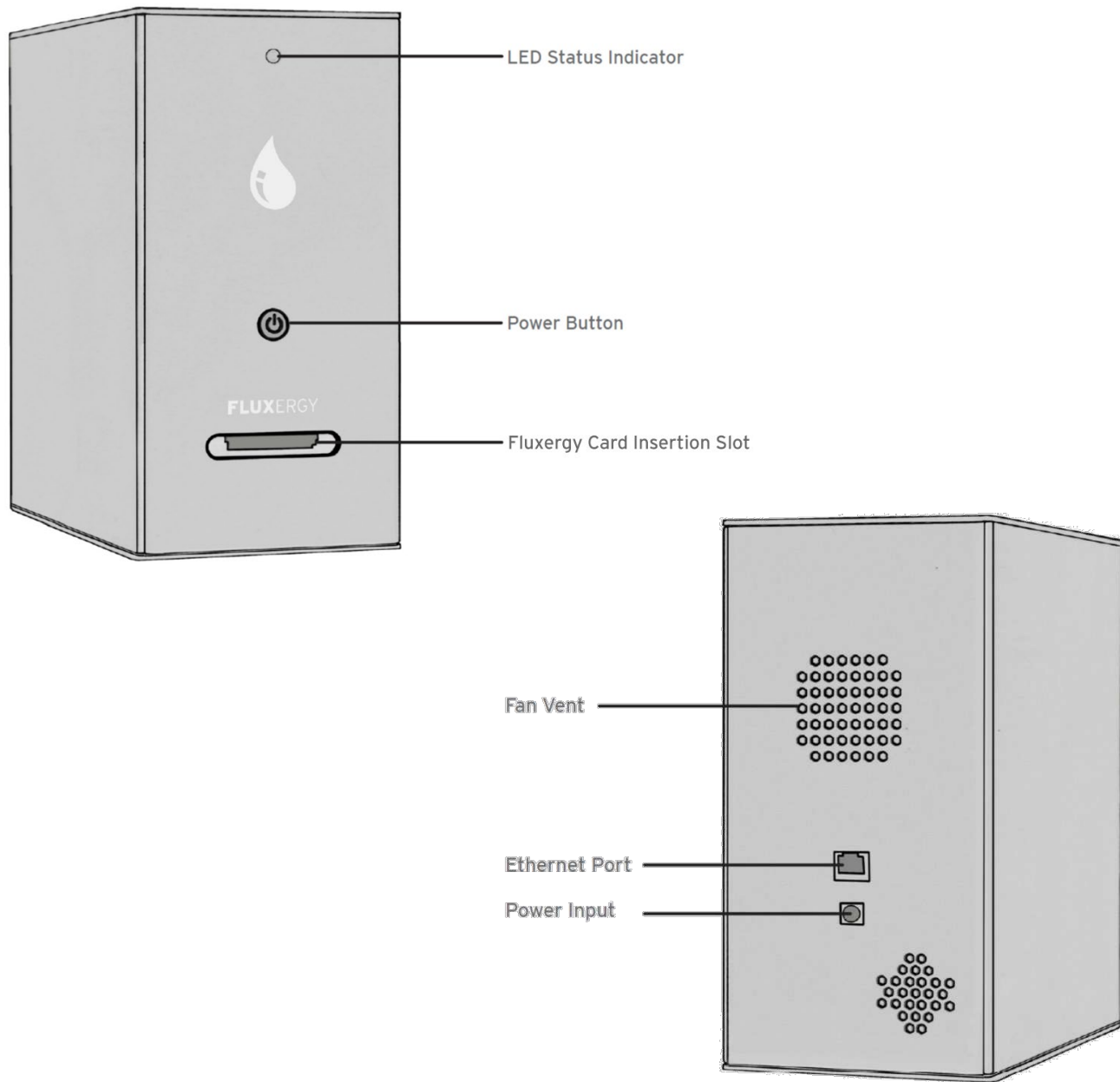


Safety Precautions

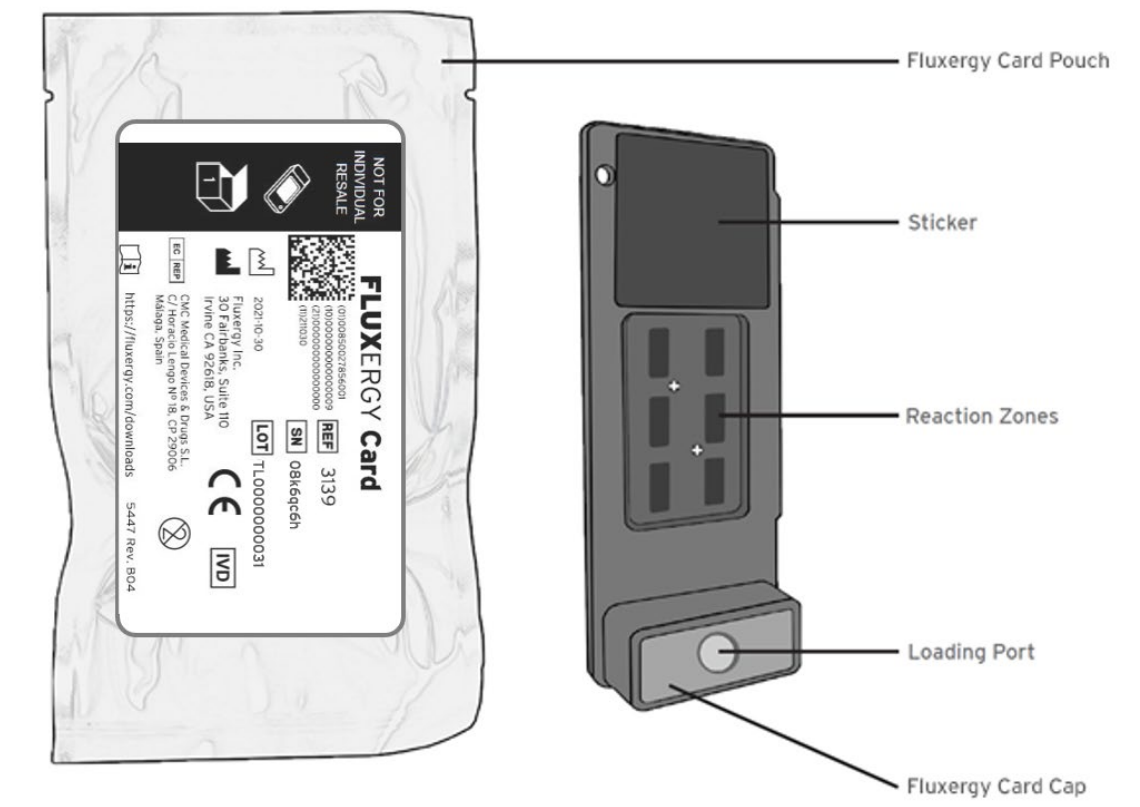
- The Fluxergy Analyzer contains no user-serviceable components. DO NOT disassemble.
- Never attempt to repair or adjust the Analyzer yourself. Unauthorized disassembly and repair could result in electrical hazards. Only a qualified Fluxergy technician can service the Analyzer. Contact Fluxergy Customer Support if the Analyzer fails to operate properly.
- Contact Fluxergy Customer Support for any service issues.
- DO NOT stack other equipment or containers on top of the analyzer.
- Keep analyzer away from sources of excessive heat or flames.
- PROTECT your equipment from damp conditions or wet weather.
- DO NOT spill water or other fluids on the analyzer.
- DO NOT use any of the following liquids, abrasives, or aerosol sprays on or near the analyzer, as they may damage the outer case and may influence test results:
 - Organic solvents
 - Ammonia-based cleaners
 - Sprays containing volatile liquids
 - Insecticides
 - Disinfectants (Outer case of device can be gently wiped down with 70% isopropyl alcohol if contaminated)
 - Air fresheners
- The Power input supply for the Fluxergy Analyzer is 12VDC, 7A. Be sure to plug all equipment into properly grounded electrical outlets.
- Use only the power supply provided. Failure to do so may cause damage to the device and/or bodily harm.
- Disconnect the power cable from the AC power outlet:
 - If the power cable becomes frayed, split or otherwise damaged.
 - If anything is spilled onto the equipment.
 - If your equipment is exposed to excessive moisture.
 - If your equipment is dropped or the case has been damaged.
 - If you suspect that your analyzer needs service or repair.
 - Whenever you clean the case.
- DO NOT use Fluxergy equipment in a manner not approved by Fluxergy.
- Clean the exterior of Analyzer before and after each use to prevent contamination and ensure trouble-free operation. Use a soft lint-free cloth and 70% isopropyl alcohol solution.

SYSTEM OVERVIEW

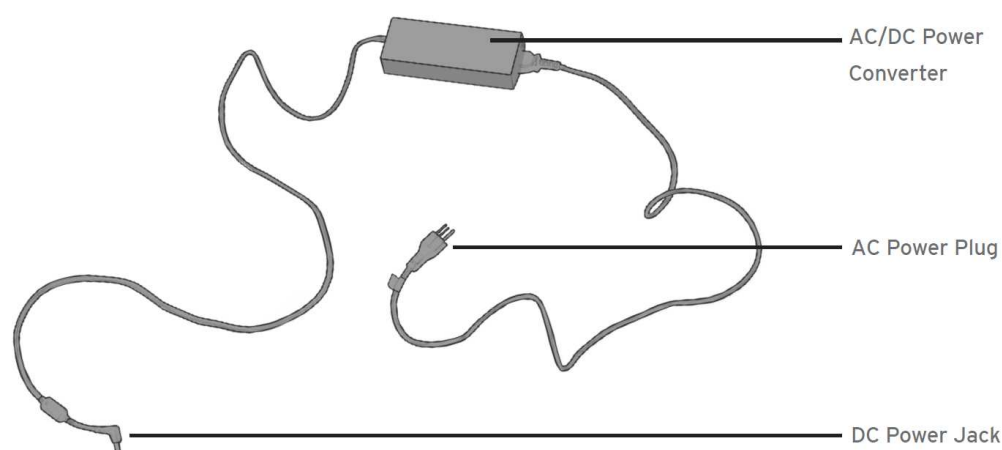
Fluxergy Analyzer



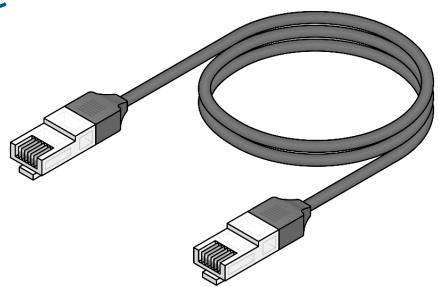
Fluxergy Card



Fluxergy Analyzer Power Cable



Ethernet Cable



Operating Conditions

	Operating	Storage
Temperature	15°C - 30°C	15°C - 30°C
Relative Humidity	10% – 85%	10% – 85%

Computer: Recommended Requirements

- Operating System
 - OS must be 64-bit
 - Windows 10 v1151
- Processor: Intel Core i5 2.5GHz or equivalent
- RAM: 8GB DDR4
- HDD: 250GB
- Screen: 1080p
- USB: 2x2.0 port (for scanner and mouse)
- Networking: Ethernet port

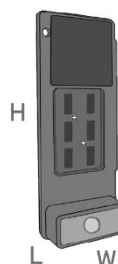
Computer: IT Recommendations

Fluxergy recommends regular backups of the PC in which Fluxergy Works is installed. In the case of a PC hardware or operating system failure, backups will allow restoration of the test history up to the last backup. Without backups, all test history on the PC will be lost if the PC suffers a non-recoverable hardware or operating system error.

Quick Specs



	Fluxergy Analyzer	Fluxergy Card
Length	26.19 cm	1.3 cm
Width	13.13 cm	4.1 cm
Height	25.8 cm	10.8 cm
Weight	6.8 kg	16.8 g (including cap)



INSTALLATION AND TROUBLESHOOTING

Setting up Fluxergy Works Software

1. Download and install the Fluxergy Works installer.
2. Enter the Registration Key provided to you by Fluxergy.
 - a. **Note: There is a one-time activation process which requires an internet connection.** Work with your IT department to ensure ports 80 (http) and 443 (https) are open. After activation internet access is no longer necessary.
3. After installing software, create an administrator account.
 - a. Note: The administrator account created at this step is the master administrator and cannot be edited by other administrator accounts.
 - b. Note: If the master administrative account password is lost, it cannot be reset. To mitigate the risk of losing all administrative access, Fluxergy recommends creating a secondary administrator account immediately after install.
4. Information regarding how to run the software can be found in the following sections.

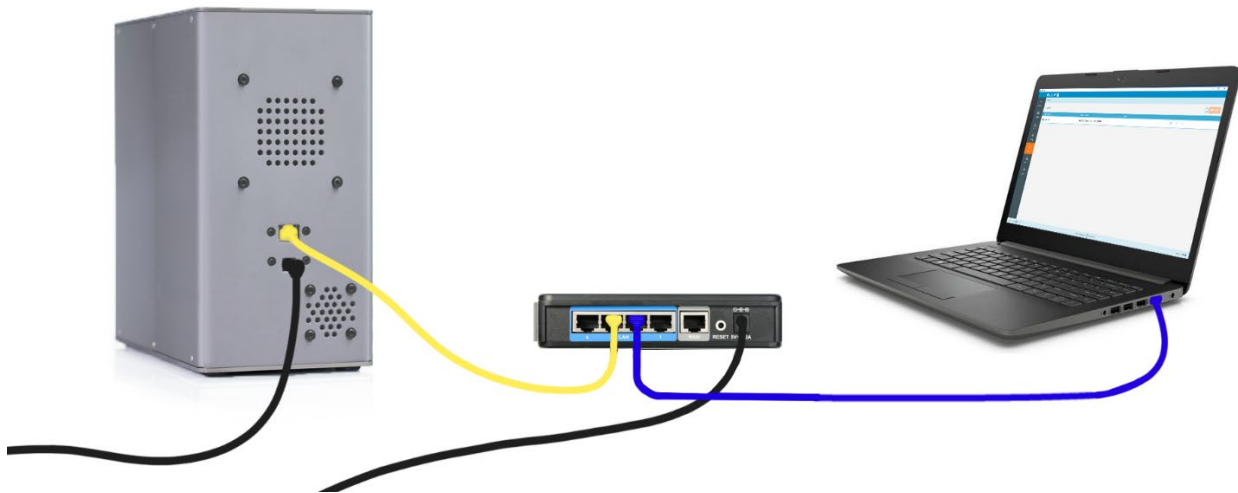
Setup Guidelines

Set up your analyzer on a level surface in a cool dry space. Make sure that the fan in the back of the analyzer will not be obstructed and that there is enough room for ventilation (at least 6 inches of space around the device).

Next, we will show you two methods of setup: creating an intranet between your device, router, and computer, and connecting your analyzer to your network.

Device Setup: Connecting with a Standalone Network

1. Plug in your Analyzer's power supply to a standard AC outlet. Plug the other end into the DC port found on the back of the Fluxergy Analyzer.
2. Connect an ethernet cable to the ethernet port found on the back of your Fluxergy Analyzer. Connect the other end of the ethernet cable to your router via the ethernet port. Do not plug into Internet/WAN port on your router.
3. Connect one ethernet cable to your computer. Plug the other end into one of the ethernet / LAN ports. Do not plug into Internet/WAN port on your router.



Device Setup: Connecting with Your Local Network

To whitelist each device within your organization's network, please work with your IT department.

1. Plug in your Analyzer's power supply to a standard AC outlet. Plug the other end into the DC port found on the back of the Fluxergy Analyzer. Turn the Analyzer ON using the front power button.
2. Connect an ethernet cable to the ethernet port found on the back of your Fluxergy Analyzer. Connect the other end of the ethernet cable to your local network.
3. Connect your computer to the same subnet as the Fluxergy Analyzer.



Troubleshooting

Issue	Steps to Take
Fluxergy Analyzer does not power up	<ul style="list-style-type: none">a) Check that the power cable to the power supply is connected to an AC outlet.b) Check the power cable is plugged into the power supply.c) Check the DC cable from the power supply is plugged into the Analyzer.d) Please contact Fluxergy Customer Support.
Fluxergy Works does not respond or is frozen.	<p>First change tabs on the sidebar and see if that fixes the issue. If not, exit out of Fluxergy Works and reopen the program.</p> <p>Please contact Fluxergy Customer Support for any other software issues.</p>
Any other Issues	Please contact Fluxergy Customer Support.

Error Codes and Their Meanings

Refer to your specific Instructions for Use for test outputs, interpretations, and actions.

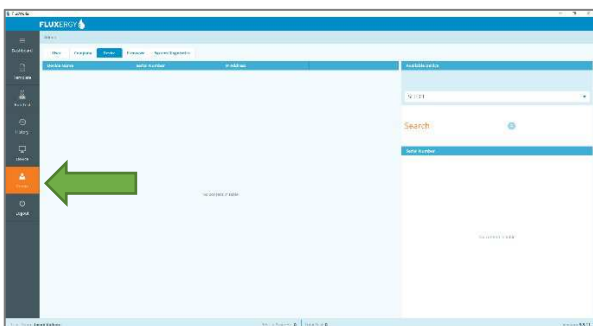
ADDING A DEVICE TO FLUXERGY WORKS

01



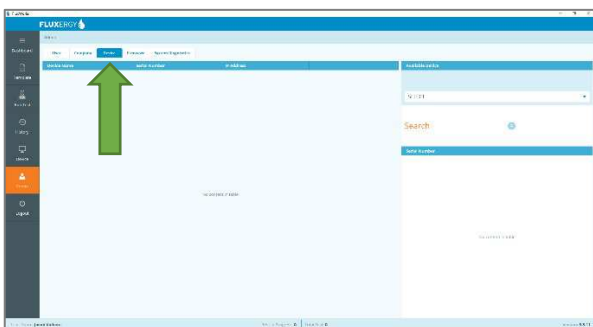
Before you connect your device to Fluxergy Works, please ensure that a network connection has been established between the device and your PC. See the installation and troubleshooting section for more information.

02



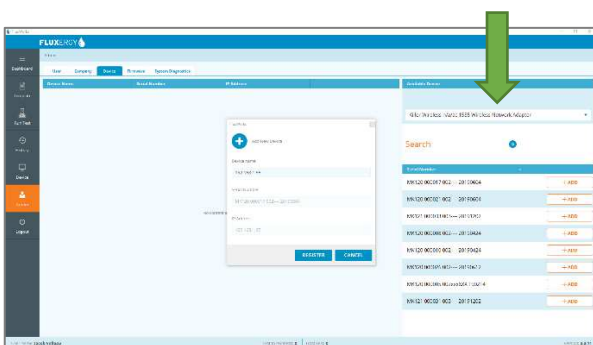
In Fluxergy Works, Click the “Admin” tab on the left side of the screen.

03



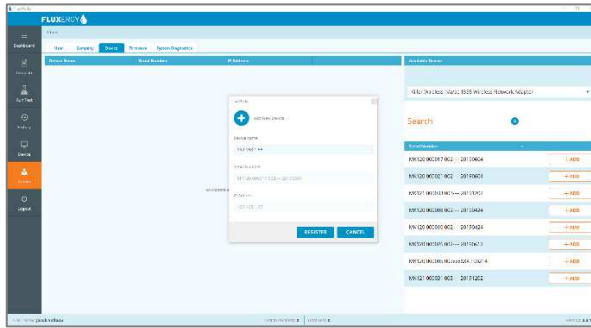
Select the “Device” tab.

04



Choose from the dropdown menu under “Network Adapter” on the right side of your screen. Choose the correct network adapter to scan for available devices. The software will scan the network for available devices.

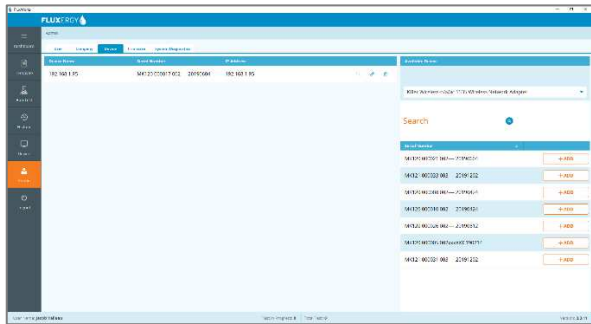
05



Select a device by clicking “Add”. If you wish, you may alter a device’s name in this window. Select register.

Note: For better identification of multiple devices, it is recommended to create a label with the device name and attach it to the corresponding device.

06



Your device will now show on the left side of your screen.

Repeat Steps 5-6 for all analyzers that will be added to Fluxergy Works.

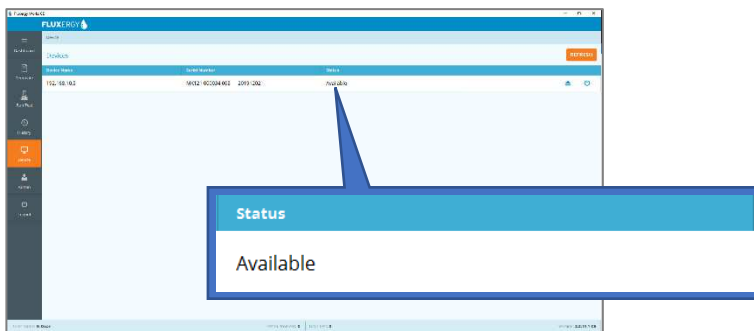
MANAGING DEVICES

Turning on your Device



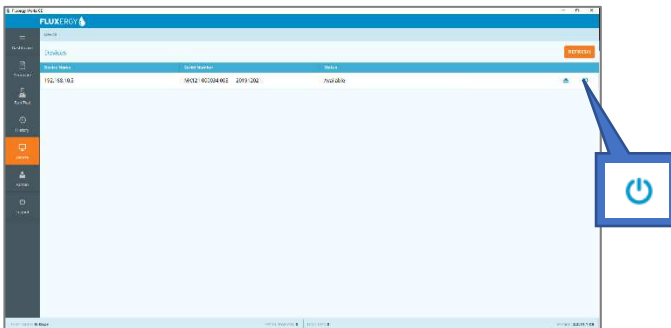
Turn on the Fluxergy Analyzer by connecting the power cord to the AC/DC port found on the back of the analyzer. Press the power button on the device. The Analyzer can remain ON when not in use. The Analyzer must be on to be found by Fluxergy Works.

Checking your Device Availability



Ensure your device is available for testing by selecting the "Device" tab on the left side of your screen. The status will show as "available" when ready to test.

Turning Off or Restarting your Device



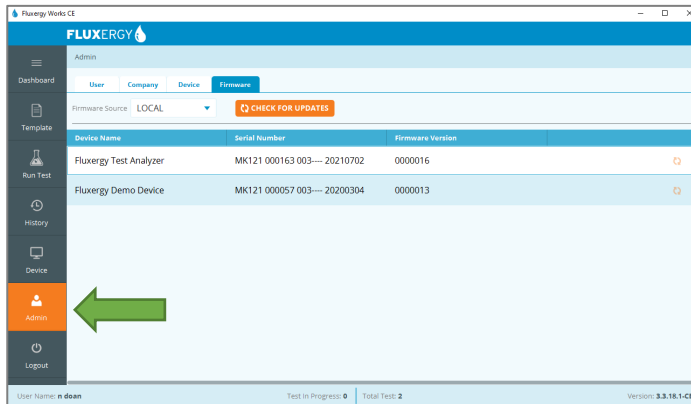
Caution: Always power off or restart the Fluxergy Analyzer from Fluxergy Works.

1. In Fluxergy Works, navigate to the "Device" tab.
2. Select the Power Button icon for the Fluxergy Analyzer device.
3. Wait 30 seconds. The front power indication LED on the device should power off.

UPDATING FIRMWARE

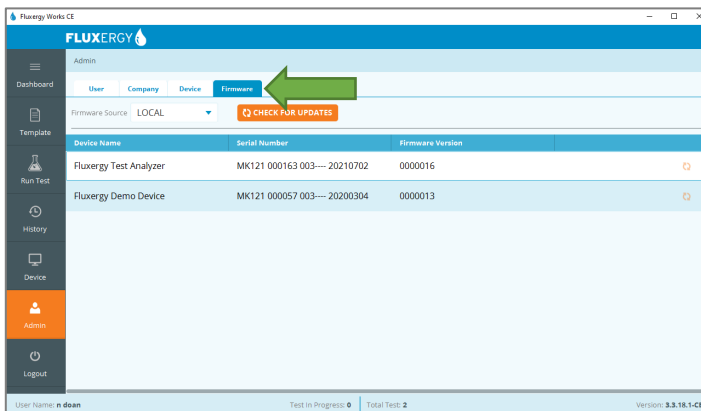
The following instructions are for updating the firmware of your Fluxergy Analyzer via Fluxergy Works. You will be notified by Fluxergy when an updated Firmware is available for download.

01



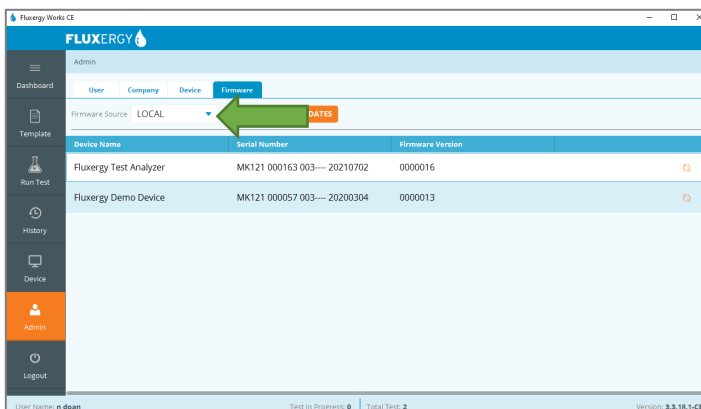
In Fluxergy Works, Click the “Admin” tab on the left side of the screen.

02



Select the “Firmware” tab.

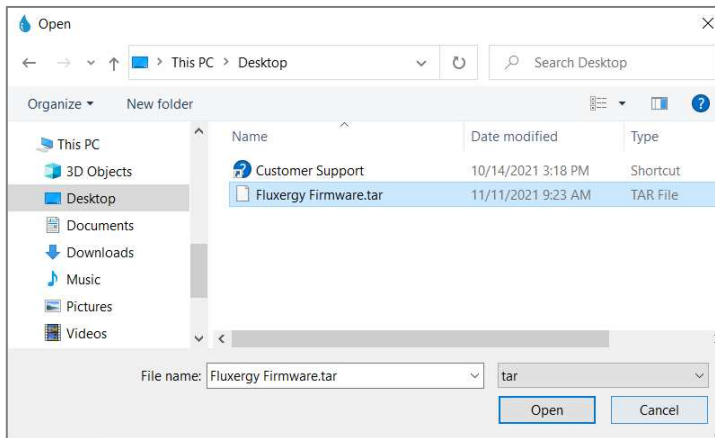
03



Select the Firmware Source dropdown, and pick “LOCAL”.

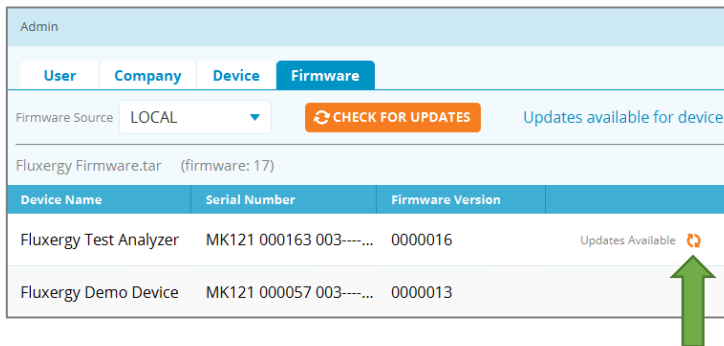
Select the “Check for Updates” button.

04



Navigate to the patch file and select it.

05



Select the update icon:

A dialogue window will pop-up briefly and then firmware installation will automatically begin. If an error message appears, please restart Fluxergy Works and try again.

06

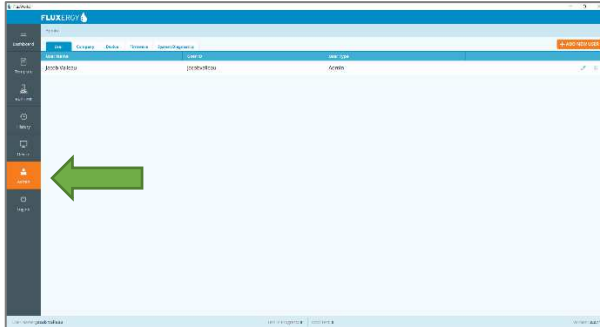
Wait approximately 5 minutes. Device will show as “unavailable” during this time.

Once device is “available” again, then you can use the system.

If you receive an error message immediately, or if the device is still “unavailable” after 10 minutes, contact Fluxergy Customer Support.

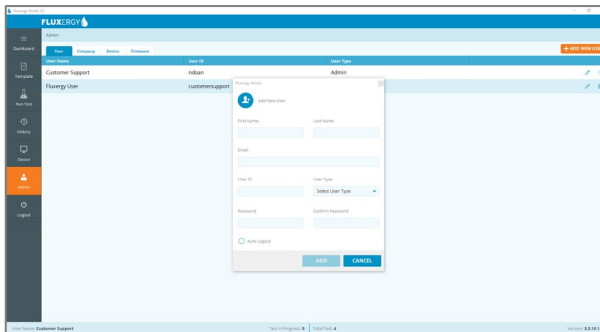
ADDING USERS & USER PERMISSIONS

01



In Fluxergy Works, Click the “Admin” tab on the left side of the screen. In the “User” tab, select “Add New User”.

02



Add your new user’s name, email, user ID, and password. Choose the level of functionality you want for the new user.

Administrator users have the following capabilities: adding devices, removing devices, adding users, removing users, viewing device statuses, editing user information, running tests, and viewing test results.

User privileges are dependent on user type. Administrator users can assign user types that have restricted functionality within Fluxergy Works.

03

Select “Add”. Your new user will display and can log in using their user ID and password.

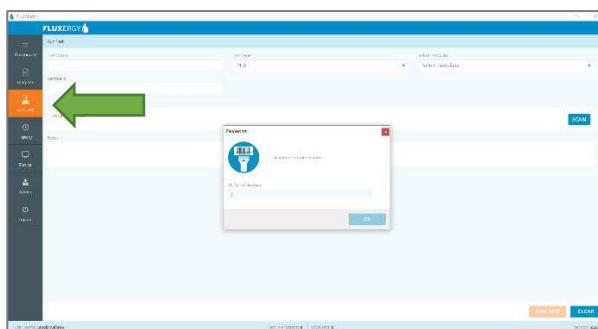
RUNNING A TEST ON FLUXERGY WORKS

01



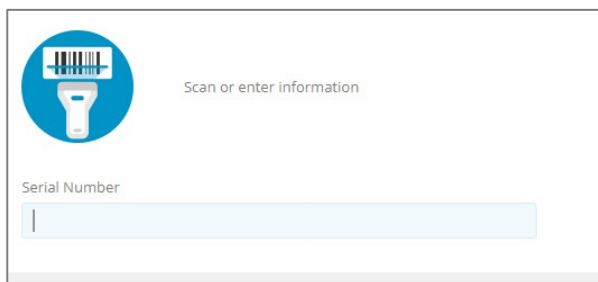
Open Fluxergy Works and log in using your user ID and password.

02



Click the “Run Test” tab on the sidebar on the left side of your screen.

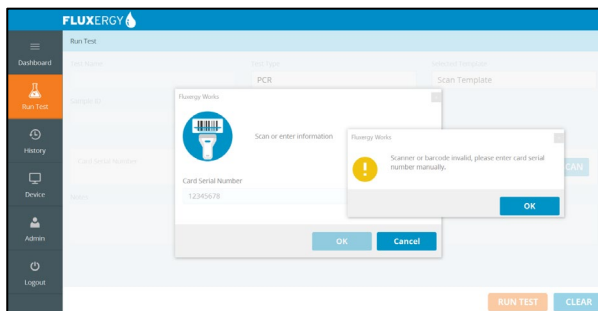
03



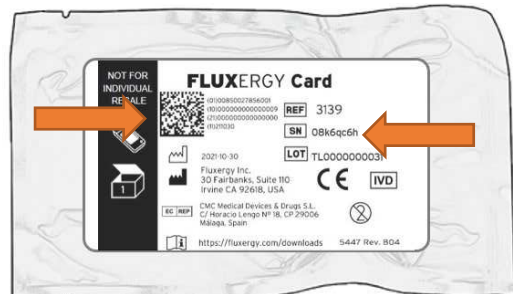
Scan the barcode on the Individual Fluxergy Card Package.

Note: For best results, ensure that the scanning surface is flat, and entire barcode can be captured.

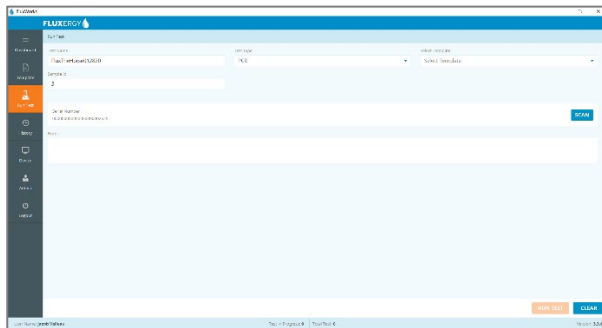
04



If the barcode cannot be scanned a prompt will appear, “Scanner or barcode invalid, please enter card serial number manually.” Click OK and enter card serial number or scan again.

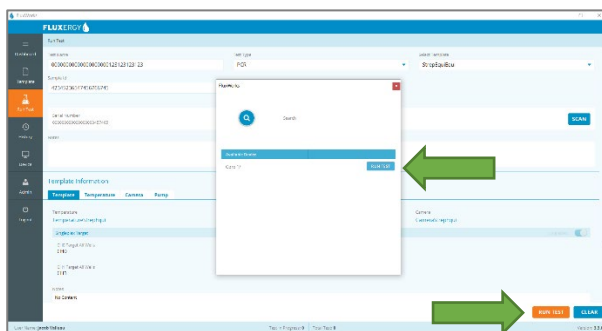


05



Add a test name and sample ID. Every test name must be unique.

06



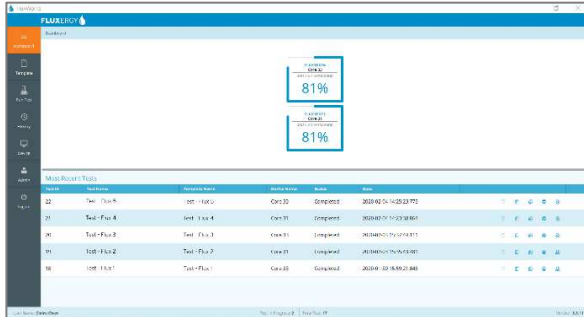
Click run test in the bottom right corner. Select your connected analyzer and click run test. Insert the Fluxergy Test Card into the device.

Once inserted, press “OK”. The analyzer will begin the assay once test card has been inserted.

Caution: Refer to Instructions for Use for specific instructions in setting up and running test!

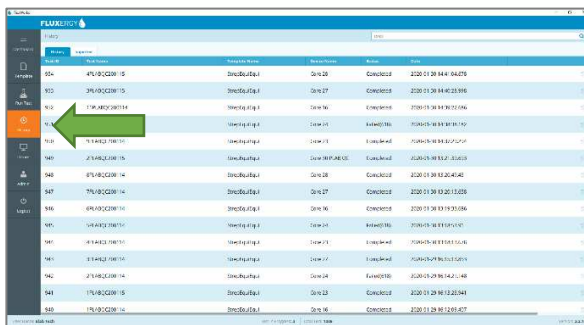
ACCESSING YOUR RESULTS

Access Tests in Dashboard



Once you select “OK” to run the test, you will be redirected to the dashboard. Here, you can find tests in progress as well as a list of your most recent tests.

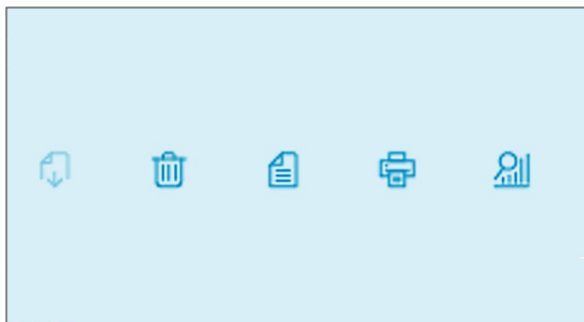
Access Tests in History



To see all tests, select the “History” tab.

On the right-hand side of the page, you can choose to delete, export, print, or view results for each test.

Manage Tests



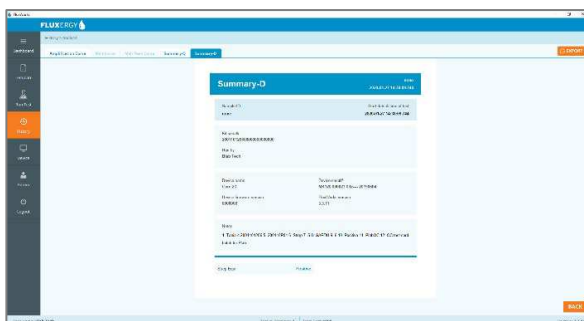
Selecting the trash icon will delete test data permanently.

Selecting the file icon will display test summary.

Selecting the printer icon will enable you to print test summaries.

Select the far-right option, the magnification glass and graph icon, to view your results. From this screen, you may export test data.

Navigating to Qualitative Results



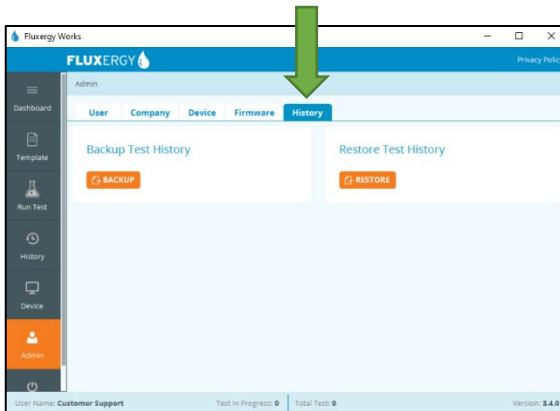
Select Summary D to see a simplified summary and qualitative result.

BACKUP TEST HISTORY

In the case of a PC hardware or operating system failure, Backups allow restoration of the test history up to the last backup.

The Backup feature creates an encrypted package with .bak file extension. The .bak file contains all test files within the test History page. You will be asked to create a password upon creation of a .bak package.

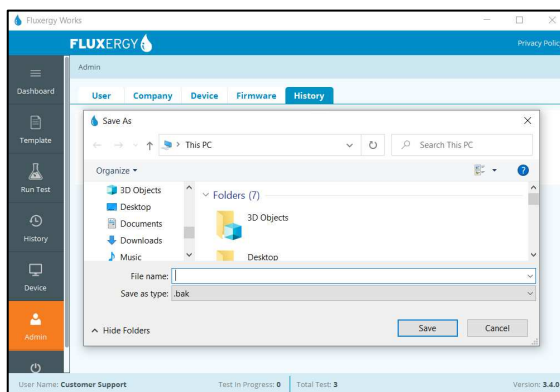
01



Navigate to “Admin” and then “History” Tab to locate the Backup and Restore buttons.

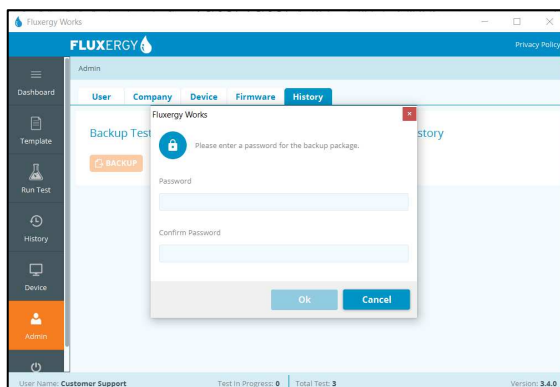
Select the Backup button.

02



A pop-up will appear and request you to select where to save your backup (.bak) package file. Chose a folder on your computer to save the .bak package.

03



Fluxergy Works will prompt you to create a password for the backup (.bak) package.

Note: Passwords cannot be retrieved if lost.

04

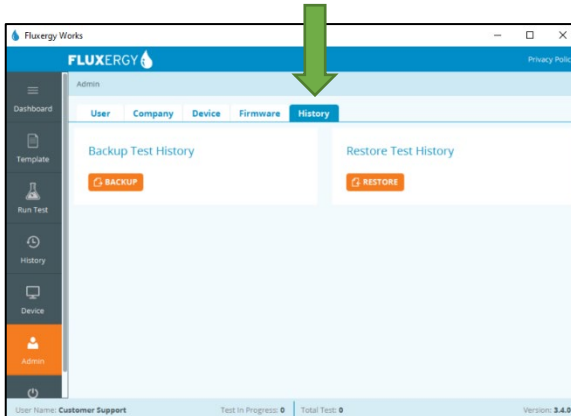
Your current entire test history is now packaged as a .bak.

RESTORE TEST HISTORY

The Restore feature loads and overwrites the entire test History with the user-selected .bak package. The contents of the .bak package will be found in “Imported” tab within the “History” page.

Warning: Restoring of test history by loading a .bak file erases and replaces all current test data stored within Fluxergy Works.

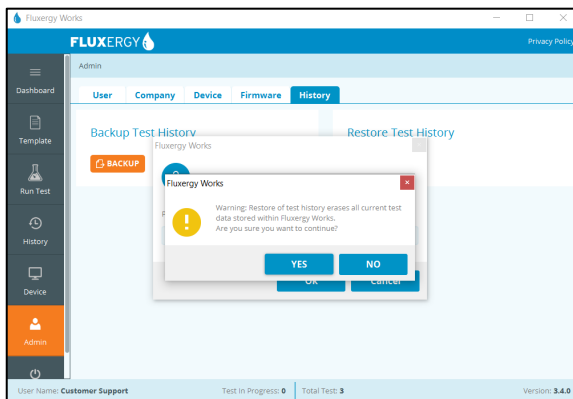
01



Navigate to “Admin” and then “History” Tab to locate the Backup and Restore buttons.

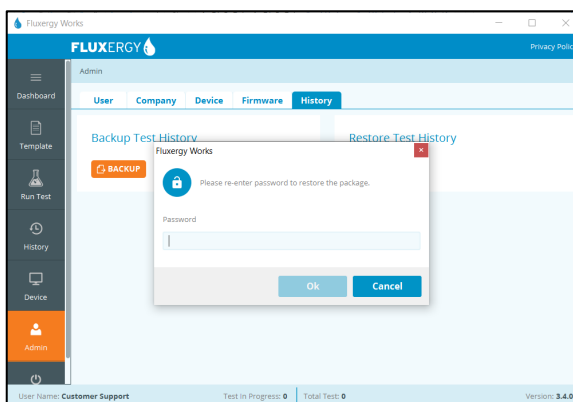
Select the Restore button.

02



A pop-up will appear and request you to open the Backup package (.bak) file. Enter the password for the .bak file. Confirm that you accept to Restore, overwriting existing test history.

03















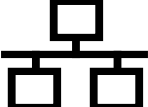


Enter the password for the .bak file.

04

Your entire test History will now be overwritten by the .bak package test files. The .bak package test files will be found in the “Imported” tab within “History”.

LABELS AND MARKING

Symbols on Packaging and Analyzer

Symbol	Meaning
	The Fluxergy product conforms to DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 1998 on in vitro diagnostic medical devices.
	This symbol indicates that the product is for In Vitro Diagnostic use.
 www.fluxergy.com/downloads	The instructions for use are either included or available for download electronically from the website shown.
	Indicates that the transport package shall be kept away from rain and in dry conditions.
 YYYY-MM-DD	Indicates the date after which the product is not to be used. The date format is YYYY-MM-DD where YYYY represents the 4 digit year, MM is the two digit month and DD is the two digit day.
	Indicates the unique device identification data.
	Indicates methods to contact customer support.
	Indicates that separate collection for waste electric and electronic equipment (WEEE) is required.
	Indicates the Fluxergy catalogue number so that the medical device can be identified.
	Indicates the Fluxergy serial number so that a specific medical device can be identified.
	Indicates the medical device manufacturer, as defined in EU Directive 98/79/EC. This symbol is used to identify the name and address of company that manufactured the product.
	Indicates the authorized representative in the European Community.
	Indicates the ethernet port location. See page 9.
	Indicates the location of the 12V DC Socket
	Indicates DC Current

CONTACT AND LEGAL INFORMATION

Fluxergy Headquarters Location



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