DASH® Rapid PCR Instrument

Model: DASH-0002

SYSTEM MANUAL

DASH® Rapid PCR Instrument Manual

REF **SG-0002**

Model: DASH-0002

IVD Rx Only

For *In Vitro* Diagnostic Use Only
For Rx Use Only

Nuclein

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Table of Contents

Chapter 1: Introduction *1*

Intended Use **1**

Product Description **1**

Warnings, Limitations, and Precautions **2**

General Safety & Security Measures **3**

Tables of Symbols **6**

Chapter 2: Installation and Set-up *7*

Unpacking Instructions **7**

Major System Components **7**

Setting Up the DASH® Rapid PCR Instrument **8**

Setting Up the Printer **11**

Starting Up the DASH® Rapid PCR Instrument **14**

Instrument Calibration 14
Powering Up 14
Ejecting the Shipping Cartridge 14
Warming Up 14
Initial Log-In 15
Connecting to the Cloud and Portal Access 16
Connecting to Wi-Fi 17
User Accessibility to the DASH Instrument and Portal 20
Administrator access to the Portal 20
Updating the GUI PIN 21
Adding a User 22
Adding a Site Location 24
Administrator Access to the Cloud-Connected DASH Instrument 25
Administrator View of the Cloud-Connected DASH Instruments in the Portal 26
Multi-Factor Authentication (MFA) Settings in the Portal 26

Chapter 3: Running QC Samples *30*

Chapter 4: Running Patient Samples *31*

Chapter 5: Logging Out and Shutting Down *31*

Logging out **31**

Shutting Down the DASH Instrument **32**

Chapter 6: Editing Settings and Viewing Reports *33*

Editing Settings **33**

Portal Settings Access 33

DASH GUI Settings Access 34

Viewing Reports **36**

Chapter 7: Maintenance & Cleaning *37*

Maintenance **37**

Routine Cleaning **37**

Over-The-Air (OTA) DASH Software Update 38
Chapter 8: Troubleshooting & Equipment Service 40
Nuclein Customer Support 41
Appendix A: DASH® Rapid PCR Instrument Specifications 42
Appendix B: DASH® Rapid PCR System Safety and Electromagnetic Compatibility (EMC) 43
Appendix C: DASH® Rapid PCR System Wi-Fi Specifications 44
Revision History 45

Chapter 1: Introduction

Intended Use

The DASH® Rapid PCR Instrument (DASH Instrument) is an automated, fluorescence-based, reverse-transcription polymerase chain reaction (RT-PCR) instrument that extracts specimens and performs nucleic acid amplified tests (NAAT) in DASH test cartridges for the qualitative detection of infectious diseases. The DASH Instrument is intended for use in conjunction with DASH Rapid PCR System tests to aid in the diagnosis of infectious diseases.

Product Description

The DASH Instrument extracts specimens and utilizes RT-PCR nucleic acid amplification technology for the qualitative detection of infectious diseases. A test cartridge consumable is required to run each test.

The test cartridge contains all the reagents required for the extraction, capture and amplification of target nucleic acid and process control. The DASH Instrument performs RT-PCR to amplify targeted nucleic acid, providing a fluorescent signal. Fluorescence is measured and an algorithm determines whether the result is Positive or Negative for each target.

To perform a test, the specimen is added to the test cartridge, the specimen chamber cap is closed, and the test cartridge is inserted into the DASH Instrument. The DASH Instrument performs sample extraction and nucleic acid amplification with results automatically reported.

The DASH Instrument is provided with a barcode scanner, printer, and paper. Additional test-specific information and workflows are detailed in the respective test *Instructions for Use* and quick reference guide.

See **Appendix A** for additional content regarding device specifications.

Warnings, Limitations, and Precautions

1. For *In Vitro* Diagnostic Use Only.
2. For Rx Use Only.
3. Before performing any test, read the DASH® System Manual and the DASH test Instructions for Use completely.
4. Any modification to the test or the manufacturer's instructions may yield erroneous results.
5. Prior to use, inspect system materials for damage that would impede functionality (e.g., cracked screen, frayed wiring, etc.). **DO NOT** use if System materials are damaged.
6. **Caution**: Use only the power supply that is provided with the System.
7. **Caution**: Only the power supply that is provided should be used with the DASH System.
8. **Caution**: This instrument is designed and tested to CISPR Class A standard. Class A equipment is suitable for all use in all establishments other than domestic/residential.
9. **Caution**: This instrument has been designed and tested to IEC 60601-1-2 and complies with emission and immunity requirements.
10. **Caution**: Always operate the Instrument on a clean, flat, level, and stable surface. **DO NOT** drop the Instrument device components.
11. **Warning**: Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment may result in increased electromagnetic emissions or decreased electromagnetic immunity of the equipment and result in improper operation.
12. **Warning**: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the DASH Instrument, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
13. **Caution**: The electromagnetic (EM) environment should be evaluated prior to operation of the device. **DO NOT** operate this system in close proximity to sources of strong electromagnetic fields (for example unshielded intentional RF sources, including electrocautery, MRI, electrosurgical units, and diathermy devices), as they may interfere with proper operations. The DASH System is intended to perform according to the claimed test error and invalid rates. If performance is lost or degraded due to EM disturbances, an operator may see an increased rate of system errors and aborted or invalid tests.
14. **Caution**: Never move the Instrument while a test is in progress.
15. **Caution**: Follow proper infection control guidelines for handling all specimens and related items. Properly dispose of all contaminated waste according to local, state, and federal requirements.
16. **Caution**: **DO NOT** disassemble or attempt to repair the DASH Instrument or other accessories, as there is a risk of damage. This Instrument does not contain serviceable parts and should be returned to Nuclein for repair.
17. **Caution**: Only operate the Instrument for its intended purpose and in accordance with this user manual and warnings. If the Instrument is used in a manner not specified in the manual, protection provided by the equipment will be impaired. This System (including power supply) is designed to operate within the manufacturer's specifications. **DO NOT** exceed the manufacturer's specifications when in use.
18. **Caution**: Position the unit with clear access to connectors. Keep connected cables clear of work areas such that tripping or catching will not pull the unit off its work bench. The main socket outlet intended for use with DASH Instrument power supply should be located near the Instrument and be readily accessible.
19. **Caution**: All test materials should be discarded as biohazard waste according to local, state, and federal regulatory requirements. Solutions used to make the positive control swab are non-infectious, however, patient samples, controls, and test cartridges should be handled as though they could transmit disease. Observe established precautions against microbial hazards during use and disposal.

20. Keep the work area clean to prevent contamination. 10% bleach (expressed as 0.6% sodium hypochlorite), water rinse step, and 70% ethanol or 70% isopropyl alcohol can be used to clean the surface of the DASH® Instrument as per the instructions provided.
21. Wear appropriate personal protection equipment (PPE) and powder free gloves when running each test and handling patient specimens. Change gloves between handling each specimen.

FEDERAL COMMUNICATION COMMISSION INTERFERENCE STATEMENT

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

⚠ ***Note**: 'Harmful interference' is defined in 47 CFR 2.1 by the FCC as follows: Interference which endangers the functioning of a radionavigation service or of other safety services or seriously degrades, obstructs, or repeatedly interrupts a radio communication service operating in accordance with the [ITU] Radio Regulations.*

⚠ **FCC Caution**: Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment.

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

(1) This device may not cause harmful interference, and

(2) This device must accept any interference received, including interference that may cause undesired operation.

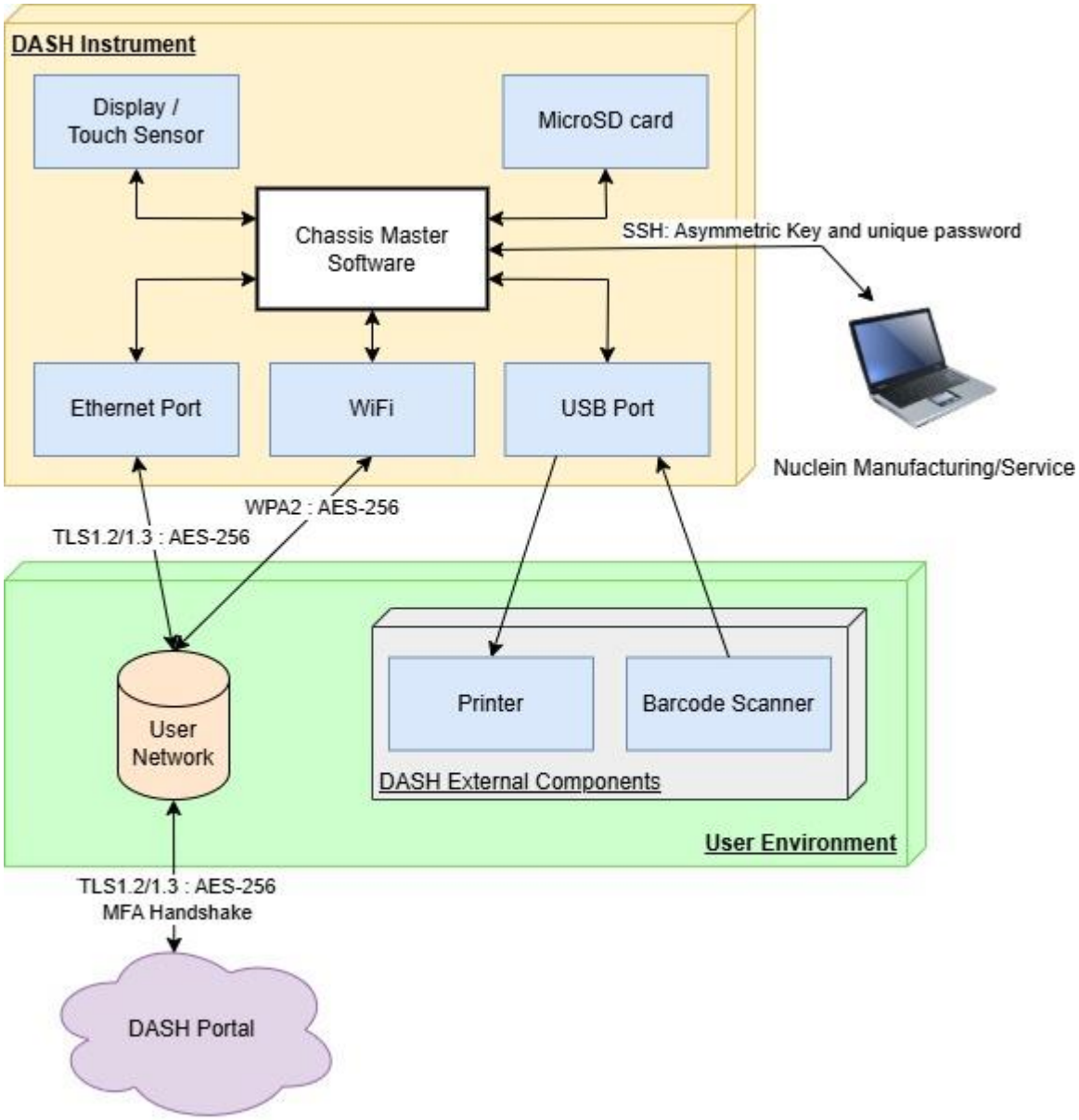
General Safety & Security Measures

Cybersecurity

Medical device security is a shared responsibility among all stakeholders. It is your responsibility to take the following security steps to protect the product:

Network Security, Critical Functionality, and Secure Configuration

Secure your network using network intrusion detection and prevention mechanisms, using adequately hardened network/application firewalls and network segmentation. A visual description of the device and cloud architecture is demonstrated in the DASH Global System Diagram below:



- As demonstrated in the DASH® Global System Diagram, the device has enhanced cybersecurity controls, including encryption to protect the device and cloud environment from cybersecurity threats.
- Hardware and communication ports are disabled and will only work with Nuclein provided accessories by their vendor and product IDs. Communication with the Cloud, if enabled, is encrypted, and the device hardware and software protections include code-signing to protect against cybersecurity events.
- The software has been tested to ensure these protections.

Product Security: Operating Environment
Nuclein recommends protecting the physical security of the DASH System and operating it in a secure manner, such as within secure access-controlled environments.

Authenticated and Authorized User Access
Restrict access to the DASH Instrument in accordance with your organization's security policies and through the user accounts created and maintained by the DASH Instrument. Authenticated users can use the system to the level enabled by their system Role. Security

permissions are based on the least-privilege principle. In general, users only use the functionality that is available for them on the cloud system and device, based on their authorization permissions. See Chapter 2 (*User Accessibility to the DASH Instrument and Portal* section) for a description of the authentication and authorization of access levels. For instructions on setting up Multi-factor Authentication (MFA), reference Chapter 2 (*Adding a User* section). Use of Multi-factor Authentication is recommended.

Sensitive Data Management
Results or other data exported from the DASH® Instrument should be controlled with appropriate laboratory practices. Chain of custody processes should be established for monitoring of sensitive data exported in accordance with your organization's data privacy policies.

Protected Health Information
When entering a Specimen ID, it is best to use non-repeating accession numbers to ensure that no Protected Health Information ("PHI"), as defined by the Health Insurance and Portability and Accountability Act ("HIPAA"), is requested, required, displayed, transmitted, or maintained on the device. Do not enter patient names, addresses, demographic information, financial information, medical record numbers, Social Security numbers, or any other unique identifying numbers, characteristics, or codes in the Specimen ID field.

Device Architecture and SBOM
A machine-readable Software Bill of Materials and additional architecture detail will be provided to verified users upon request. Please contact Customer Support for additional information.

Software Updates
Nuclein provides software updates over an encrypted SSH connection. Please refer to *Chapter 7 - Maintenance and Cleaning (Over-The-Air (OTA) DASH Software Update)* section and contact Customer Support for further information.

Notifications, Resiliency, Backup and Restore Functionality
The cloud System is hosted on AWS (Amazon Web Services), and all system data (in- and outbound) is delivered over secured and encrypted communication channels to protect the device software from cybersecurity events. AWS provides security services such as vulnerability notifications, system resiliency as well as system back-up processes.

Software for the device is provided in a code-signed configuration. Restoration following any corruption or fatal error events will be performed by Nuclein. Please contact Customer Support for additional information.

The device maintains an audit log of hardware and software commands and events. This log is not accessible to the end user; however, the log is available upon request by verified users by contacting Customer Support.

End of Life and Support
At the end of support, the company may no longer be able to reasonably provide security patches or software updates. If the device needs to remain in service following the end of support, the company will communicate the potential cybersecurity risks through the vulnerability disclosure process.

To decommission your device, return to Nuclein where all memory and data will be destroyed. Contact Customer Support to initiate a return.

Table of Symbols

Symbol	Meaning	Symbol	Meaning
REF	Catalog Number		Caution; Consult accompanying documents
SN	Serial Number		Manufacturer
	USB 2.0 High Speed interface connector		On-Off Power Button
IVD	In vitro Diagnostic medical device	Rx Only	Prescription Device
	Consult Instructions For Use	UDI	Unique Device Identifier
	Flat side on the bottom	UL LISTED	Underwriters Laboratories Listed
	Do not use if package is damaged		Date of Manufacture
	Direct current		

Chapter 2: Installation and Set-up

Unpacking Instructions

Remove all components from their shipping containers and be sure to identify each item to confirm that you have received everything. Inspect components for any obvious signs of damage. Please immediately report any damaged or missing components to Nuclein Customer Support.

Major System Components

- Instrument
- Cartridges
- Software/Graphical User Interface (GUI)

The following items are supplied with the DASH® Rapid PCR Instrument in two boxes.

- SG-0002 | DASH Rapid PCR Instrument
    - DASH Rapid PCR Instrument
    - Wi-Fi Antenna
    - System Manual
- SG-0004 | DASH Accessories Kit
    - Power Adaptor
    - Power Cord
    - Barcode Scanner
    - Printer and Paper
    - Printer Cable

Setting Up the DASH® Rapid PCR System

Warning: DASH® System must be located on a level surface.

DO NOT place system near sources of strong electromagnetic fields.

The DASH System should be set up on a clean and level surface at least four (4) feet wide and two (2) feet deep. Two 120VAC outlets are required for plugging in the Instrument and printer power adapter. Only use the Nuclein supplied power cable and power adapter.

The environmental conditions for operating the Instrument are 15°-30°C, 20%-80% relative humidity. The Instrument is intended for indoor use in dry locations in an office or laboratory at altitudes up to 1,676 meters (5,500 feet).

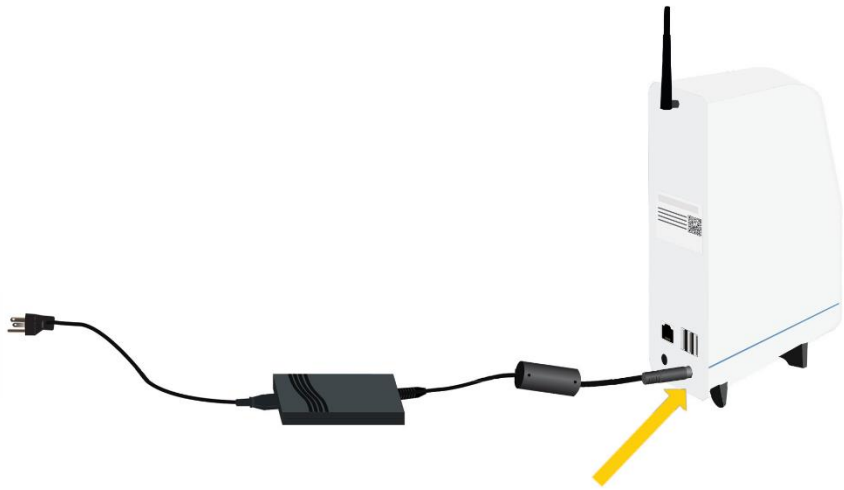
The System is most easily set up as shown in the images that follow. Plug the power cords and cables into the back of the Instrument. In case of emergency, note that the final arrangement of all System components should allow for rapid plug removal from the power outlet.

1. Turn the DASH Instrument so the back side is facing forward to make it easier to plug in cables.

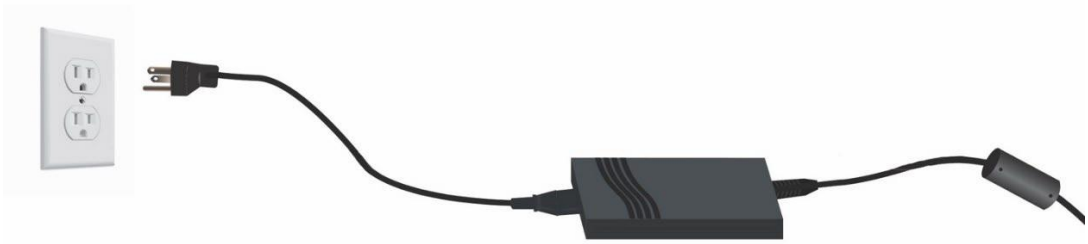
2. Rotate the Wi-Fi antenna on the back of the DASH® Instrument clockwise so that it is facing straight up. Tighten the knob next to the Instrument if needed to hold it firmly in place.

3. Connect the barcode cable to the back of the barcode reader, then connect to any one of the USB ports and set it in front of the work area.

4. Connect the DASH® Instrument's power adapter to the round socket on the back of the DASH Instrument. The flat side of the plug should be up.

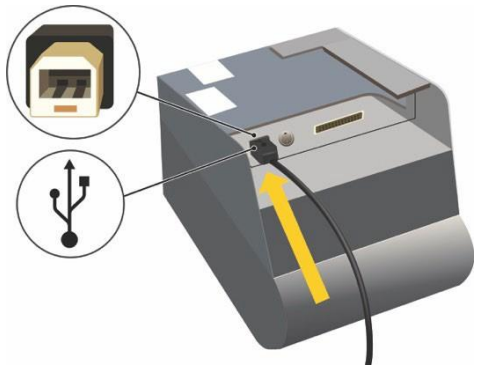


5. Connect the power cord to the adapter, then plug power cord into 120VAC outlet.



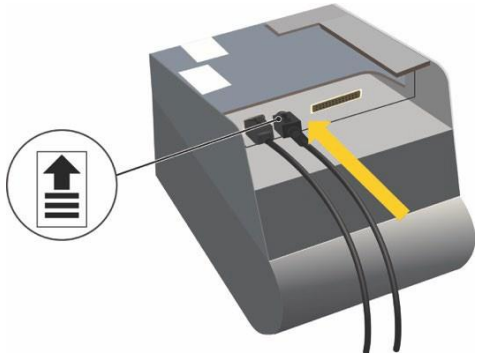
Setting Up the Printer

1. Turn the printer upside down so it is easier to plug in the cables.
2. Insert USB cable's square plug into the printer's square socket, with the USB connect icon facing the bottom of the printer.



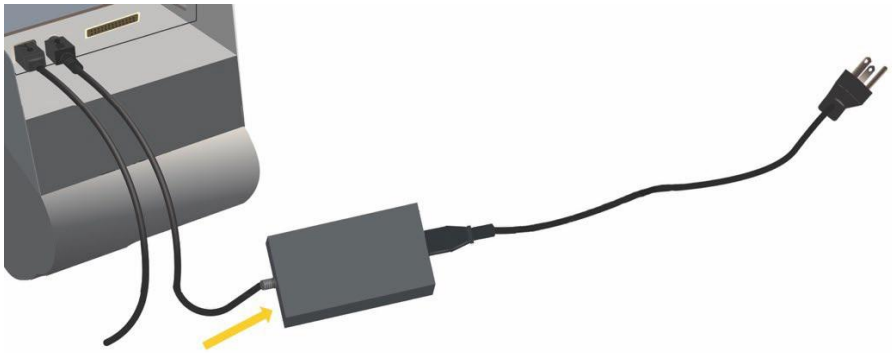
3. Plug the other side of the USB cable into the back of the DASH® Instrument.

4. Insert the round plug of the power adaptor cable into the printer.



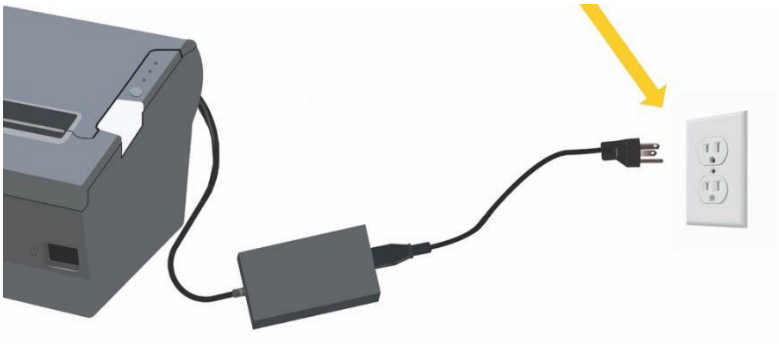
***Note**: The flat side with the arrow should face the bottom of the printer.*

5. Plug the power cord into the power adapter.

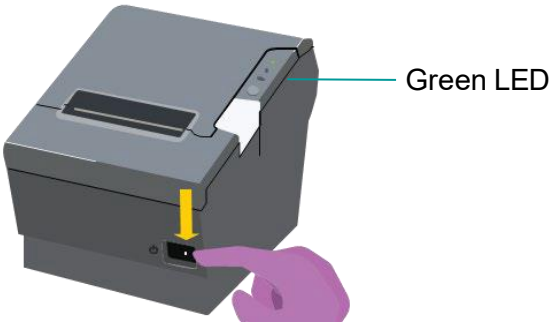


6. Turn the printer right side up.

7. Plug power cord into 120VAC outlet.

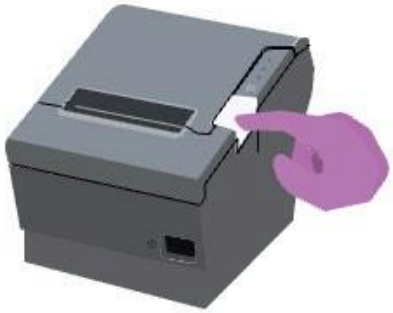


8. **Power up the printer**. Push the white dot side of the power switch on the front of the printer.



***Note**: The green LED on the top right side will illuminate when power is on.*

9. **Check thermal paper**. Open the printer lid by pressing the grey button on the right side of the printer.



***Note**: Inside the printer box, you will find a roll of thermal paper wrapped in black plastic.*

i. Remove the thermal paper from the printer box.

ii. Remove the plastic wrapping from the roll of paper and place it in the printer as depicted in the Step 10 image that follows.

iii. The end of the roll of thermal paper should feed from the bottom towards the front.

10. Pull the end to unroll six inches of paper.

11. Close the printer lid.

12. Tear off excess paper by pulling it forward over the tear bar and slightly to the side.

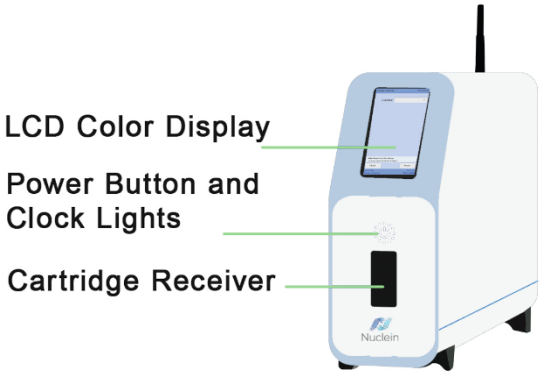
Starting Up the DASH® Rapid PCR Instrument

Instrument Calibration

The DASH® Instrument is factory calibrated and does not require any further calibration and verification.

Powering Up

1. Press the power button in the center of the DASH Instrument's "Clock Lights".



On Backside: 3 USB Connections; 1 Wi-Fi Antenna; 1 Ethernet Port; and Power Connection.

2. The software operating system will initiate, displaying a series of screens.

Ejecting the Shipping Cartridge

During the initialization process, the DASH Instrument begins warming-up and will then display an "Eject Cartridge" button.

1. Tap the "Eject Cartridge" button. The door will slide open, and the Cartridge will be ejected.
2. Remove the shipping Cartridge from the carrier.

   ***Note**: Retain the shipping Cartridge. The shipping Cartridge should be reinstalled whenever the DASH Instrument is shipped. To reinstall the shipping Cartridge, scan the barcode of the shipping Cartridge, tap "Open" on the DASH Instrument, and insert the shipping Cartridge.*

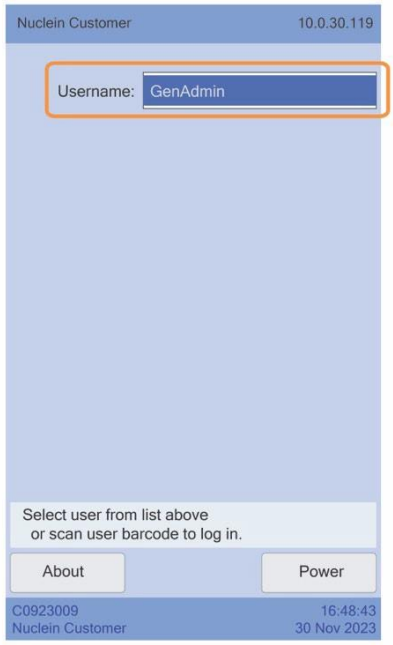
Warming Up

After the shipping Cartridge is removed, the DASH Instrument will continue warming up. When preset temperatures are reached, operators can log in and begin processing Cartridges.

***Note**: the warmup step should take approximately 5 minutes or less. If it takes more than 15 minutes or there is an error on the GUI, please contact Customer Support.*

Initial Log-In

1. After Instrument warmup, the Username menu will appear, with a single option of "GenAdmin" appearing:



2. After selecting "GenAdmin" option, the pre-set PIN, 00000, should be entered by the organization's designated administrator.

***Note**: After five (5) incorrect login attempts, users will be temporarily locked out from the system. Contact your Site Administrator or Nuclein Customer Support to reset your password.*

Connecting to the Cloud and Portal Access

The DASH® Instrument is a standalone device that does not require cloud connectivity to function. However, cloud connectivity is supported via wireless or ethernet and provides the optional operational experience enabling the following functions via the Portal:

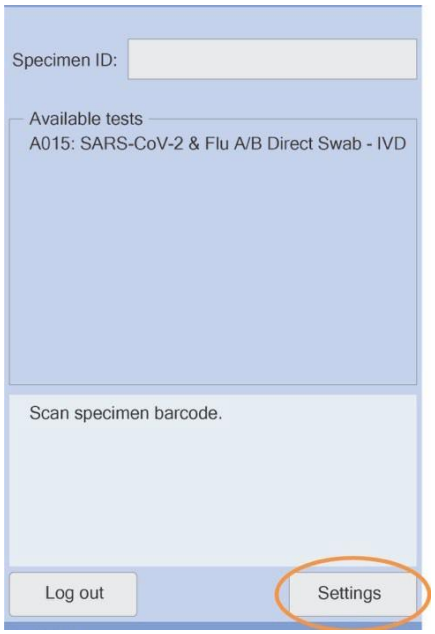
- The addition of operators, to be able to log in to the DASH Instrument individually (see “Add a User” section below)
- The ability of the administrator to edit some DASH settings via a portal (see “Edit Settings” section of Chapter 6). These settings are also accessible by the administrator through the GUI, as noted in Chapter 6
- The ability of the administrator to access the Reporting feature (i.e., previously run specimen results) via a portal (see “Viewing Reports” section of Chapter 6)
- The ability of Nuclein Customer Support to download DASH logs for the purposes of troubleshooting
- Changing the PIN of the administrator and/or any operators created
- The ability to perform future software updates remotely, as needed

If cloud connectivity is not chosen, please proceed to Chapter 3 – Running QC Samples. The use of the DASH Instrument will only be through use of a GenAdmin login and not individual operators.

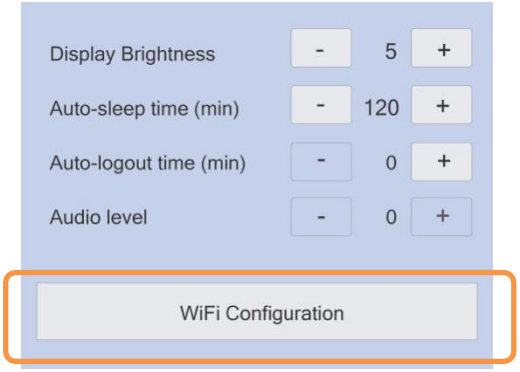
Connecting to Wi-Fi

1. After initial log-in, you will see a “Settings” button in the lower right corner.

2. Tap “Settings”.



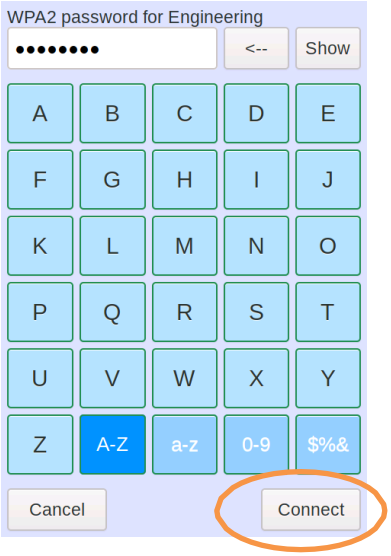
3. Tap “Wi-Fi Configuration”.



4. Ensure that “Enable Wi-Fi” is selected. The list of available Wi-Fi sources will be displayed.

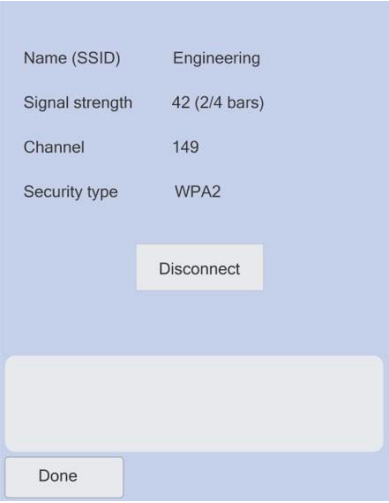
5. Choose the Wi-Fi source to connect.

6. Tap “Configure” to enter the Wi-Fi password, then Tap “Connect”



7. Once connected to Wi-Fi, the screen will show the signal strength of the Wi-Fi connection and an option to disconnect from Wi-Fi.

   Note: *Once connected, you should see the blue "F" at the bottom the GUI. Establishing connection can take upwards of 20 minutes, depending on signal strength and other factors. Restarting the DASH may help push this connection, and if not, please contact Nuclein Customer Support by emailing customersupport@nuclein.com or calling (888) 992-DASH.*



Note*: If Wi-Fi connectivity is not feasible, please contact your internal IT department to connect your Instrument to the internet via ethernet.*

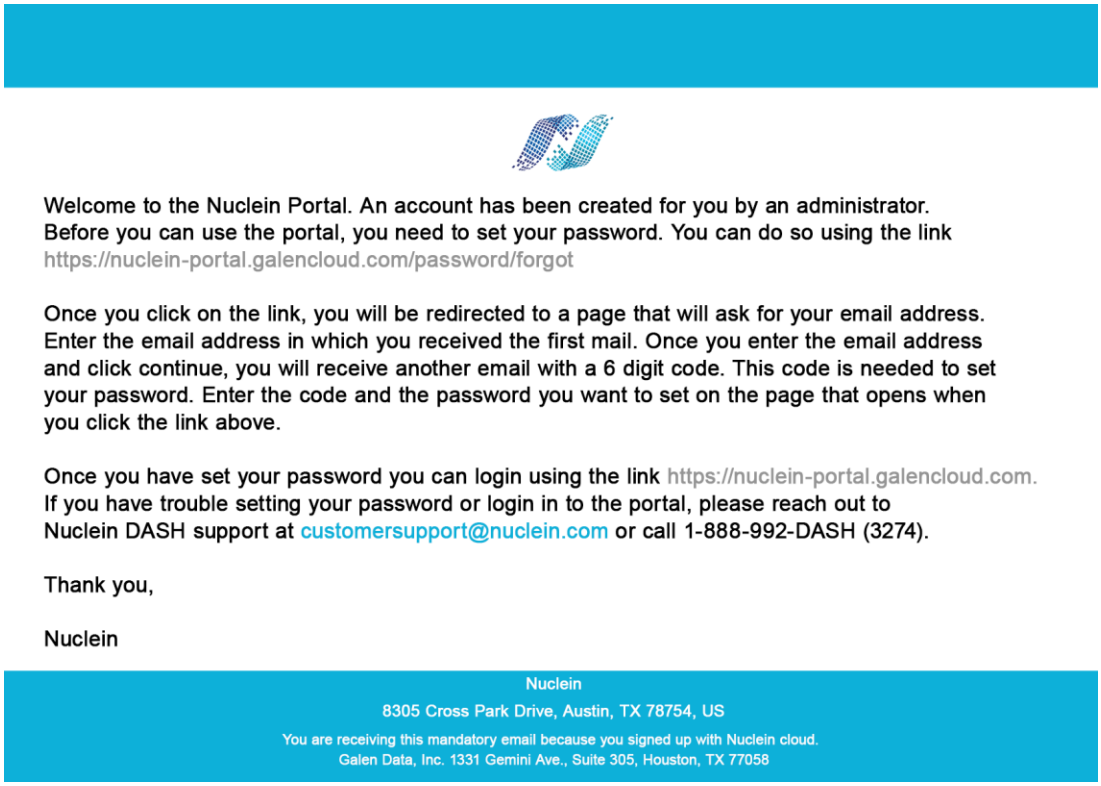
8. After connecting the DASH® Instrument to the internet, contact Nuclein Customer Support by emailing customersupport@nuclein.com or calling (888) 992-DASH to gain access to the portal. You will need to provide Customer Support with the DASH serial number, the name of your organization, and the name and email address of the Administrator for the DASH Instrument.

User Accessibility to the DASH® Instrument and Portal

Function	Organization Administrator	Operator
Login to Portal	Yes	No
View Reports	Yes, only for user's Organization	No
Create/Update/Delete User	Yes, only for user's Organization	No
View List of Instruments	Yes, only for user's Organization	No
View User List	Yes, only for user's Organization	No
Login to Instrument	Yes, only to DASH instruments assigned to Organization	Yes, only to DASH instruments assigned to Organization
Create/Update/Delete Sites	Yes, only to DASH instruments assigned to Organization	No

Administrator Access to the Portal

After contacting Nuclein Customer Support, the organization's Administrator will receive an automated email with a link to the portal for password reset. The email will have the following format:



Welcome to the Nuclein Portal. An account has been created for you by an administrator. Before you can use the portal, you need to set your password. You can do so using the link https://nuclein-portal.galencloud.com/password/forgot

Once you click on the link, you will be redirected to a page that will ask for your email address. Enter the email address in which you received the first mail. Once you enter the email address and click continue, you will receive another email with a 6 digit code. This code is needed to set your password. Enter the code and the password you want to set on the page that opens when you click the link above.

Once you have set your password you can login using the link https://nuclein-portal.galencloud.com. If you have trouble setting your password or login in to the portal, please reach out to Nuclein DASH support at customersupport@nuclein.com or call 1-888-992-DASH (3274).

Thank you,

Nuclein

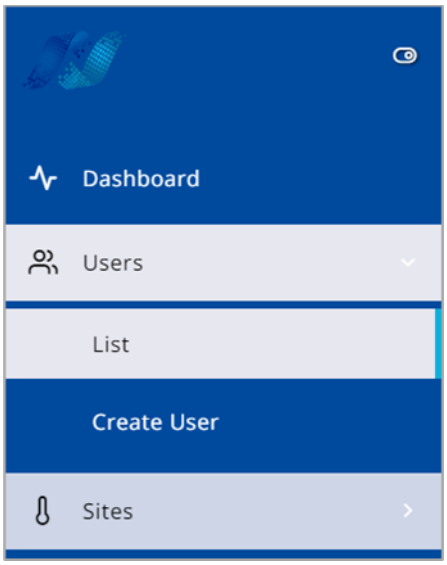
Nuclein
8305 Cross Park Drive, Austin, TX 78754, US
You are receiving this mandatory email because you signed up with Nuclein cloud.
Galen Data, Inc. 1331 Gemini Ave., Suite 305, Houston, TX 77058

***Note**: Content shown above is only for illustration.*

After this initial password reset, the Administrator will have the ability to access the features of the portal. Only the designated Administrator will have the ability to access the portal, using the associated email address and password.

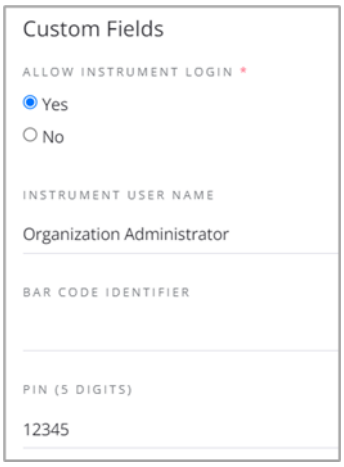
Updating the GUI PIN

1. Go to the Users section in the upper left corner of the portal, then select “List”:



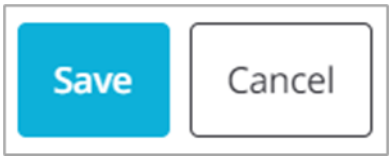
2. Select “Edit” under the “Actions” column:

3. Under the “Custom Fields” section, ensure “Allow Instrument Login” is marked as “Yes”. Update the PIN in the PIN (5 Digits) field.



***Note**: This change will go into effect within 5-20 minutes.*

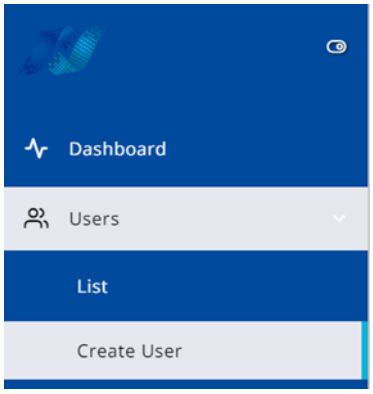
4. Select “Save” to apply changes.



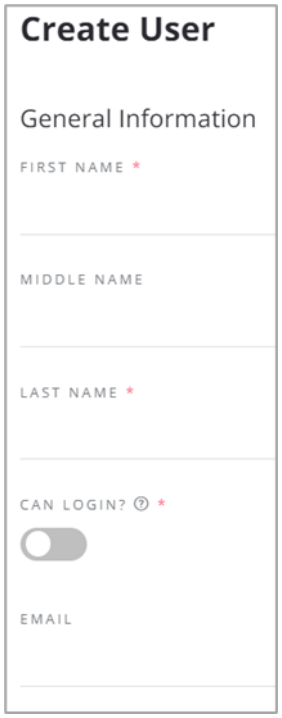
Adding a User

The Organization Administrator can create additional Operator log-ins via the portal (https://nuclein-portal.galencloud.com) following these instructions:

1. Under the “Users” module in the upper left corner, tap “Create User”.



2. Populate the First Name and Last Name.

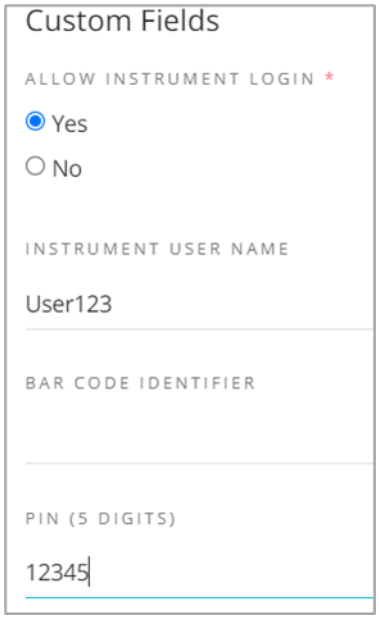


Note: *Site Users will not be able to log in to the portal. Ensure the “CAN LOGIN?” tab is set left to inactivate login.*

3. Tap the drop-down menu under the “Role” field and select “Site User”.

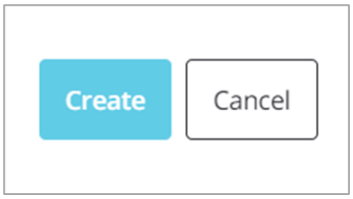
4. The “Organization” will be preset. Populate the “Site” field using the drop-down menus.

a. Tap “Yes” under “Allow Instrument Login” and assign a “Username” and “PIN (5 Digits)” Instrument PIN for the intended user.



***Note**: The “Bar Code Identifier” field is optional. Contact Nuclein Customer Support for additional guidance.*

b. Select “Create” to finish creating User.

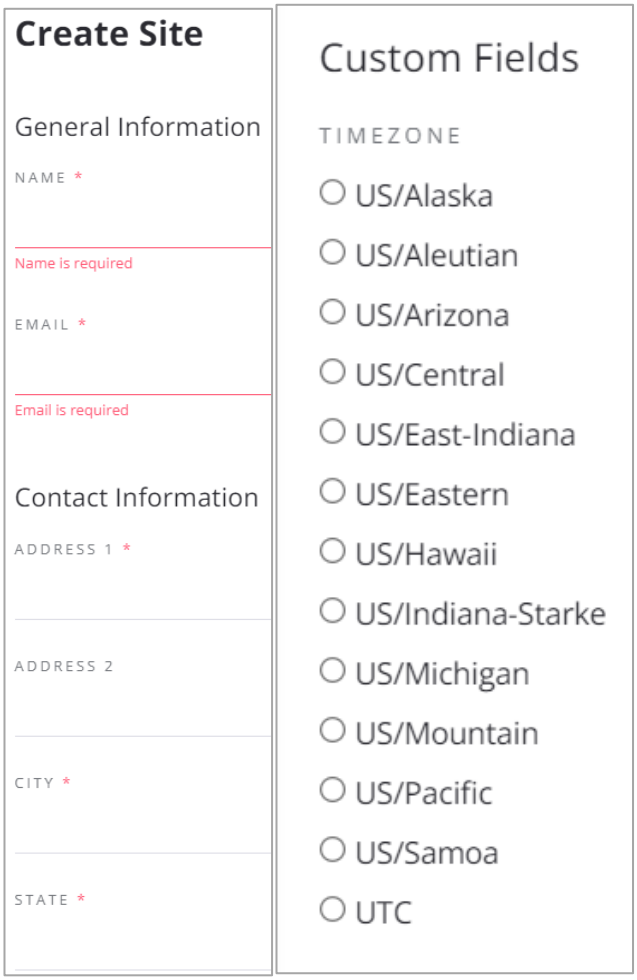


***Note:** The User’s PIN can be updated by the Administrator using the same process as in the **Updating the GUI PIN** section (page 21).*

Adding a Site Location

If an Organization has multiple locations, the Organization Administrator can create additional Site locations via the portal (https://nuclein-portal.galencloud.com) following these instructions:

1. Under “Sites” on the upper left corner of the page, select “Create Site”.
2. Enter the General Information, Contact Information, and Time Zone for the Site.

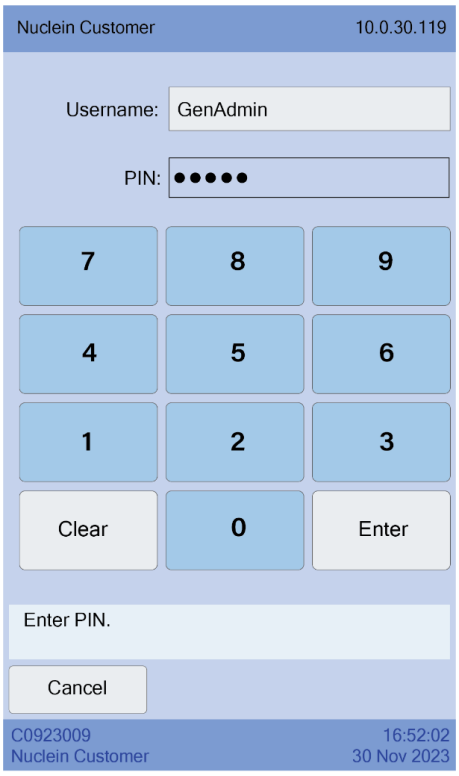


3. Select “Create” to finish the setup.

Administrator Access to the Cloud-Connected DASH® Instrument

1. After contacting Nuclein Customer Support, the DASH® Instrument will automatically register within the Cloud.

2. To indicate that the registration process is complete, the organization name on the upper and lower left corners of the screen will have changed from “Nuclein Customer” and the Username of “GenAdmin” will no longer be present:



***Note**: This process may take up to 20 minutes after connecting to Wi-Fi. If this does not occur after 30 minutes, re-start the Instrument.*

3. The organization’s Administrator will have a PIN created by Nuclein Support for logging into the DASH Instrument. The Administrator can subsequently log in to the DASH Instrument via the GUI.

4. After a few minutes, the new username will appear in the drop-down menu of users to allow the new user to log in to the Instrument.

5. To confirm that a new user has been added, select the “Username” drop-down menu to view the new username. Alternatively, the Administrator may log out or restart the Instrument to allow the new user to log in.

6. The DASH® Instrument is now ready to allow the new Operator to log in.

Administrator View of the Cloud-Connected DASH Instruments in the Portal

The Organization Administrator can view the DASH Instrument(s) associated with the Organization via the portal (https://nuclein-portal.galencloud.com) following these instructions:

1. Tap on the “Instruments” tab in the upper section of the Dashboard:

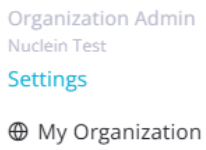
2. The DASH Instruments associated with the Organization will be listed.

Multi-Factor Authentication (MFA) Settings in the Portal

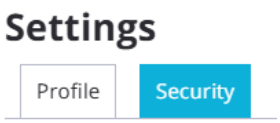
Multi-Factor Authentication (MFA) is a required function for the use of portal. The Organization Administrator has the ability to choose among three different options for receiving MFA codes when logging in to the portal.

1. In order to view these MFA options, the Administrator would log into the portal and navigate to the profile button in the upper right corner of the portal:

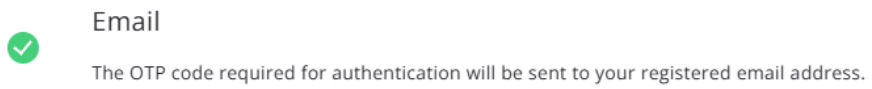
2. The Administrator would select “Settings” from the drop-down menu:



3. Under the Settings option, choose the Security tab:

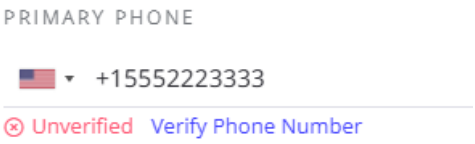


4. In the Multi-Factor Authentication (MFA) section, there are the three options for receiving authentication codes:
   a. Email; if this is the chosen method, a 6-digit code will be sent to the email address associated with the Administrator and will be entered in the portal upon initial log-in.

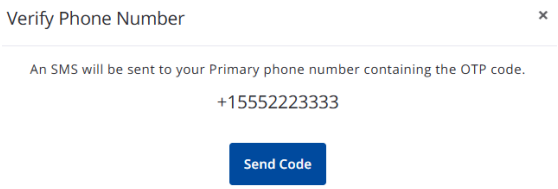


   b. SMS; if this is the chosen method, the Administrator must first verify their phone number under the Profile tab of Settings:

The “Primary Phone” field must be completed and “Verify Phone Number” chosen:

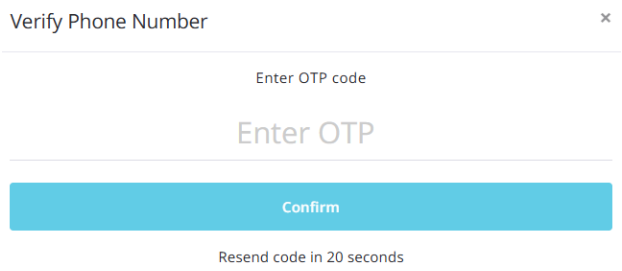


There will be a pop-up notification that an SMS text will be sent to the primary phone number identified:

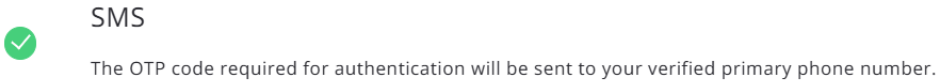


Upon receipt of the SMS text with the 6-digit code, enter that code in the “Enter OTP” field of

the subsequent pop-up notification:



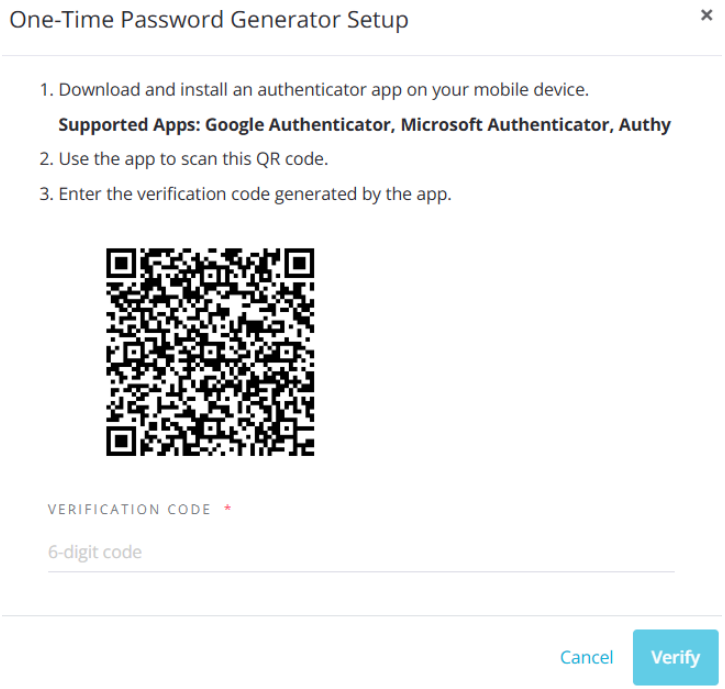
The Administrator will then be able to select the SMS option:



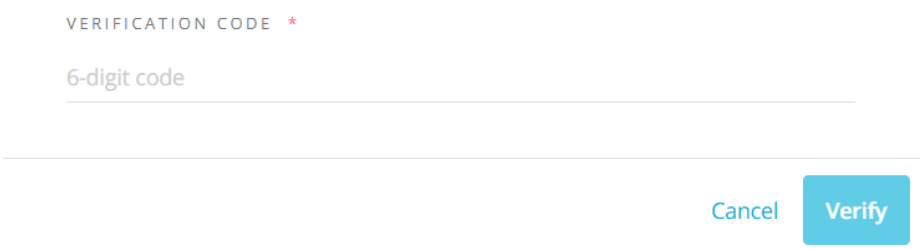
Once chosen, all subsequent portal log-in attempts will result in the MFA authentication code being texted to the verified phone number from the Administrator's profile.

c. One-Time Password Generator; if this is the chosen method, the Administrator must first verify their authenticator app under the Security tab of Settings:

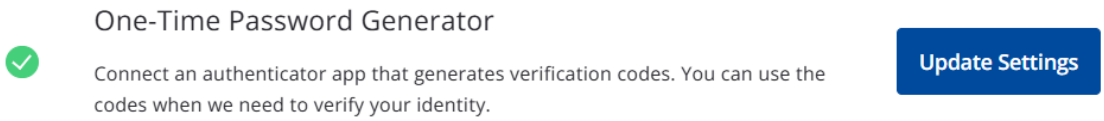
A pop-up for setting up the One-Time Password will appear with instructions to get a verification code generated by the preferred authenticator app from the supported apps list:



Enter the verification code in the “Verification Code” field:



The Administrator will then be able to select the One-Time Password Generator option:



Once chosen, all subsequent portal log-in attempts will result in the MFA authentication code being generated by the preferred authenticator app from the Administrator’s profile.

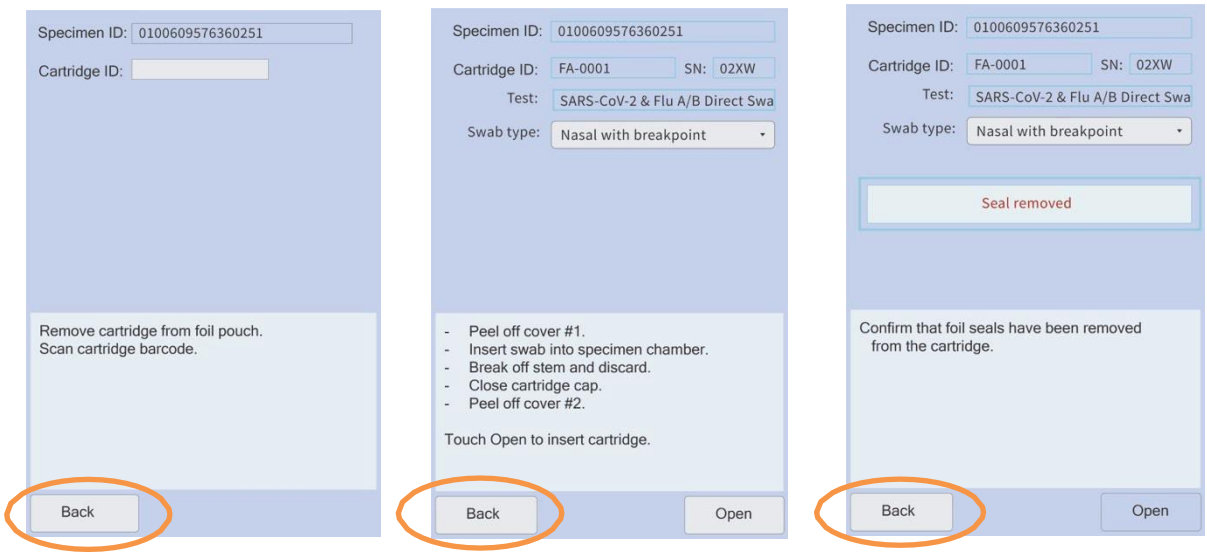
Chapter 3: Running QC Samples

Quality controls (QC), such as those used with the DASH® Rapid PCR Instrument, are designed to confirm that the test cartridge and Instrument are functioning as intended. External controls are to be tested at the times noted below:

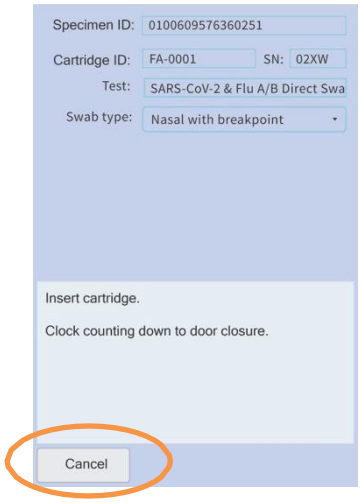
- Each time a new lot of test cartridges are received.
- Each time a new operator performs the test.
- When the DASH Instrument is used for the first time for a specific test.
- As deemed additionally necessary by internal quality control procedures, and in accordance with local, state, and federal regulations or accreditation requirements.

Refer to the appropriate test specific external control *Instructions for Use* for additional information on how to use, how to interpret the expected results, and additional QC test frequency requirements.

***Note**: At each of the steps of scanning a Specimen ID, scanning a Cartridge ID, and confirming that the foil seals have been removed, there is an option to tap the "Back" button to return to the previous field in the event of an error.*



***Note**: Upon tapping the "Seal removed" button, this "Back" option is no longer available while the Instrument is awaiting insertion of a cartridge. However, the action can be cancelled up to the point of inserting a cartridge.*



Chapter 4: Running Patient Samples

CAUTION: DASH® test cartridges may have varying CLIA Complexity levels. Please ensure the CLIA Complexity of the test you are using is appropriate for your laboratory.

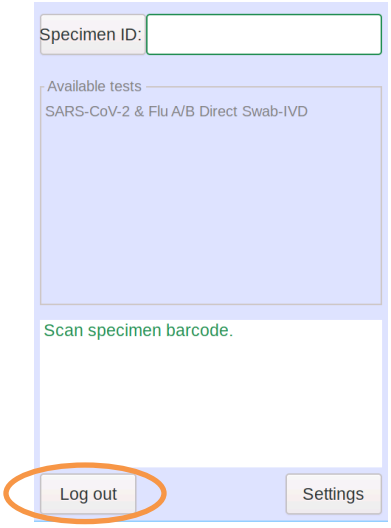
Refer to the appropriate test “Instructions for Use” and expected values.

See Notes in **Chapter 3**.

Chapter 5: Logging Out and Shutting Down

Logging out

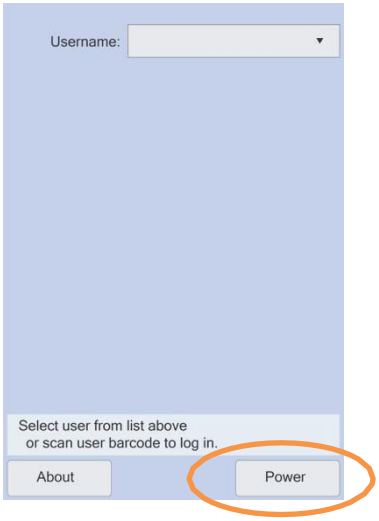
1. Tap the “Log out” button when you are done running tests.



***Note**: Once logged out, you will no longer be the active user and the button will change to “Log in”. The DASH Instrument will then remain warmed up in a standby state. The duration of the standby time is based upon a pre-determined Auto-logout time (Instrument defaults to a two-hour timeframe). The standby mode is observed by a green flashing light while the GUI screen is blank. After a period of no activity, the Instrument will switch to a lower power standby mode. See **Chapter 7** for additional detail regarding the Auto-logout feature.*

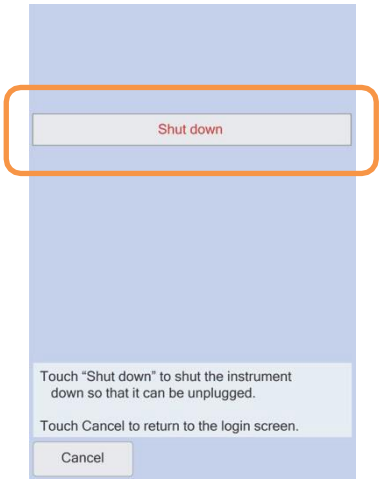
Shutting Down the DASH® Instrument

1. Tap the “Power” button.

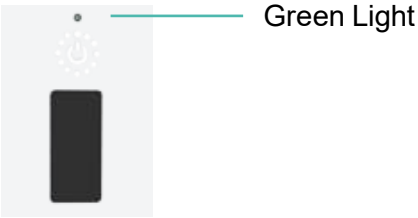


***Note**: The “Shut down” button will appear after touching the “Power” button.*

2. Tap the “Shut down” button If no more tests will be run for the day.



***Note**: Although shutting down causes all DASH® Instrument internal power to be turned off, the green light above the power button will remain on when the Instrument is shut down.*



***Note**: The DASH Instrument should only be unplugged after it has been shut down and all power turned off.*

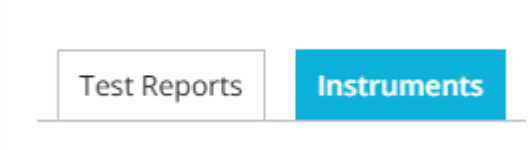
Chapter 6: Editing Settings and Viewing Reports

Editing Settings

Users with administrative privileges can make changes to some of DASH® Instrument settings through the portal or from the DASH GUI.

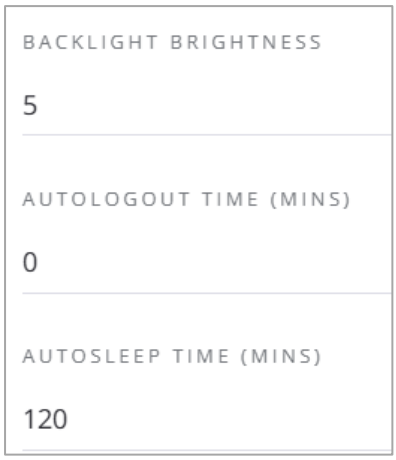
Portal Settings Access

These settings are accessed by selecting the “Instruments” tab in the portal:



On the Instrument list are all accessible instruments. To edit Instrument settings, click on “Edit” next to the instrument.

The changes are limited to *Backlight Brightness*, *Auto-logout Time*, and *Auto-sleep Time*, which all appear on the same screen, as shown below (Portal view):

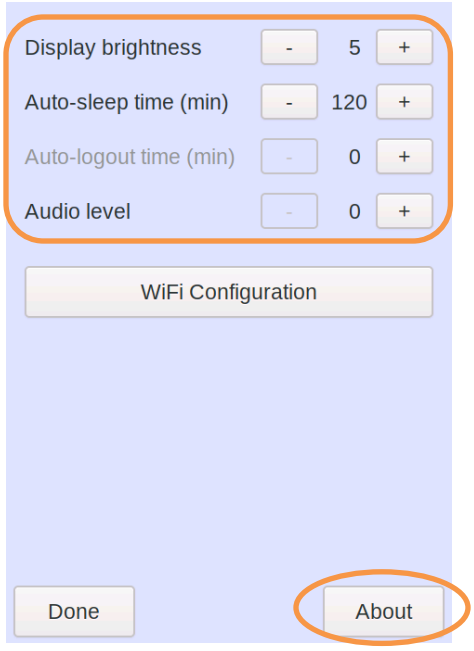


- **Backlight Brightness**: Sets the brightness of the screen, with 1 being the darkest and 7 being the brightest. The default setting is 5.
- **Auto-logout**: The time (in minutes) of inactivity at which the software will log out any user that is logged in. As a default, the software does not have this feature activated until a specific timeframe is entered by an administrative user.
- **Auto-sleep**: The time (in minutes) of inactivity at which the Instrument will go into standby mode. The default is 120 minutes.

DASH® GUI Settings Access

1. Once logged into the Instrument, tap the “Settings” button on the lower right corner.

2. Select the desired setting for each of the available categories: Display brightness, Auto-sleep Time, Auto-logout Time, or Audio level.



***Note**: The "About" button is present on the GUI when:*

(i) An administrator is logged into the Instrument under "Settings", or

(ii) When no users are logged in, on the home screen.

***Note**: The "About" button allows you to view pertinent Instrument information, which includes the instrument serial number (SN), site address, IP address, and Time Zone, among others.*

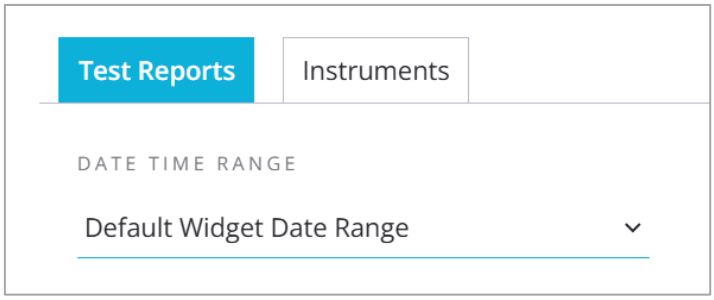
***Note**: "Wi-Fi Configuration" is also viewable under Settings. See **Chapter 2**, Section "How to connect to the cloud" for instruction regarding this option.*

Please contact Nuclein Customer Support for additional information regarding access-related inquiries.

Viewing Reports

For users with administrative privileges, the portal may be used to view a history of results.

1. Log into the portal: https://nuclein-portal.galencloud.com
2. Select the “Test Reports” option and modify the “Date Time Range” for the reports in question:



Chapter 7: Maintenance & Cleaning

Maintenance

The DASH® Instrument is maintenance-free, requires no user-based calibration, and has no serviceable parts. Discontinue use and contact Nuclein in case of Instrument failure (e.g., repeat failure of external control tests) or damage.

Routine Cleaning (Only as Needed)

Keep the work area clean to prevent contamination. Clean the exterior surfaces of the DASH Instrument using the following instructions:

- **DO NOT** use excess liquid such that it is dripping from the cloths or wipes.
- **DO NOT** spray solutions directly onto the devices.
- **DO NOT** immerse in water or cleaning solutions.
- **DO NOT** disassemble the Instrument for cleaning.
- **DO NOT** clean with soap or solutions other than those described below.

1. Moisten a lint-free wipe with a 10% bleach (expressed as 0.6% sodium hypochlorite) solution.
2. Wipe the DASH Instrument exterior. Wait two (2) minutes.

   Note: *Change lint-free wipes frequently while wiping.*

3. Moisten a lint-free wipe with water.
4. Wipe the parts described above.

   Note: *Change lint-free wipes frequently while wiping.*

5. Moisten a lint-free wipe with either 70% ethanol or 70% isopropyl alcohol.
6. Wipe the parts described above with the alcohol solution.

   Note: *Change lint-free wipes frequently while wiping.*

7. Discard used wipes accordingly in trash.

Over-The-Air (OTA) DASH® Software Update

The software updates for the DASH® Instrument are available to instruments connected to the customer portal through Wi-Fi or Ethernet connection. If there is no connection to Wi-Fi or Ethernet connection and it is necessary to upgrade the software, please contact Nuclein Customer Support.

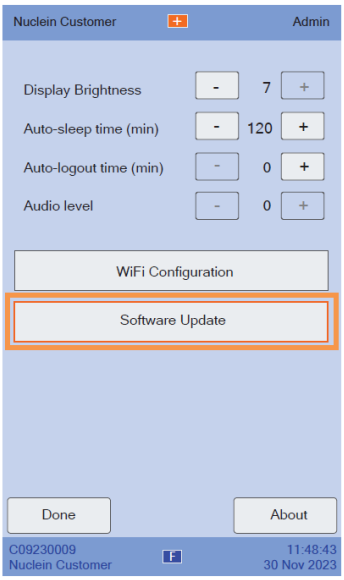
Note: *Operators will not be able to initiate or perform the software update. An administrator will need to log in for the update on the DASH Instrument to be executed.*

1. Once Software ***X.Y.Z*** is available, the Graphic User Interface (GUI) of the instrument will have an orange "+" at the top of the screen, when the DASH Instrument is on.

2. The organization administrator will log into the DASH Instrument and click on the orange "+" at the top of the screen.

3. Select the "Settings" button, with the orange outline (reference above image).

4. Select the "Software Update" button with the orange outline.

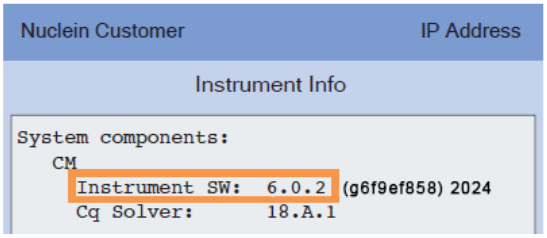


5. Confirm the software version for installation is correct and select the “Install” button with the orange outline.

6. The instrument will immediately restart and warm up.

7. When the instrument has finished warming up, select “About” and scroll to the System Components section. Confirm that the Instrument SW line reflects that version ***X.Y.Z*** of software that was pushed OTA.

Note: *You do not have to be logged into the DASH for this step.*



Chapter 8: Troubleshooting & Equipment Service

The DASH® Instrument contains no user-serviceable parts. Contact Customer Support if you have issues with your DASH Instrument. For the return of the DASH Instrument and its accessories, please contact Customer Support to assist with arrangements.

⚠ ***Note**:* Upon return of your DASH Instrument to Nuclein, all device memory and data will be destroyed, whether the instrument is decommissioned or returned to service.

Examples of Potential Error Messages:

Code	GUI Message	Explanation	Action
N/A	Cartridge was not inserted within the expected time.	Cartridge was not inserted within the expected time of 24 seconds.	Re-open the door of the DASH and proceed with inserting the cartridge.
N/A	Wrong cartridge was inserted (barcode did not match).	Incorrect barcode was read or time-out error occurred during cartridge insertion.	Re-open the door of the DASH and proceed with the correct cartridge.
N/A	Cartridge was not fully inserted.	Cartridge was not inserted completely within the expected time of 24 seconds.	Re-open the door of the DASH and proceed with re-inserting the cartridge.
N/A	Cartridge door open too long.	Cartridge was not removed within the expected time of 24 seconds when the door was opened at the end of the run.	Time-out error at end of run. Re-open the door and remove the cartridge before it times out.
N/A	Cartridge was not completely removed.	Cartridge was not fully removed within the expected time of 24 seconds when the door was opened at the end of the run.	The cartridge was not fully removed within the expected time. Re-open the door and remove the cartridge before it times out.
0x25000002	Failed - tip dock error	Instrument didn't properly grab the LTC (pipette) inside the cartridge.	Per Warnings and Precautions, Line 6, verify the presence of the LTC (Pipette & Filter). Repeat per *Patient Sample Retest Procedure* section of the Test Instructions For Use.
0x25000013	Failed - Pressure wet filter error	DASH instrument experienced a pressure fluctuation due to a wet filter and aborted the run in progress.	Repeat per *Patient Sample Retest Procedure* section of the Test Instructions For Use.
0x25000015	Failed - Motor move encoder mismatch error	Possible motor homing issue.	Re-start the DASH and run positive and negative controls. If controls pass and without a repeat of the error, issue is resolved. If the error returns after DASH re-start, please contact Nuclein Customer Support.
0x230myyzz	Failed - Motor error detected	Motor error: Where m = specific motor identified.	Re-start the DASH and run positive and negative controls. If controls pass and without a repeat of the error, issue is resolved. If the error returns after DASH re-start, please contact Nuclein Customer Support.
0x2301270A	Motor controller error; Please contact service	The cartridge was inserted too forcibly, causing a motor to shift.	Re-start the DASH and run positive and negative controls. If controls pass and without a repeat of the error, issue is resolved. If the error returns after DASH re-start, please contact Nuclein Customer Support.
0x22002xxx*	Heaters failed to reach expected temperatures within the allotted time.	Heater error: where x = specific heaters identified. GUI message may or may not contain a specific error code.	Ensure the DASH instrument is being used within the parameters specified in the “Operating environment” section of Appendix A. If within operating environment parameters, contact Nuclein Customer Support.

*For specific error code 0x22002001, separate DASH instruments about 1 inch to 2 inches apart from each other. Re-

start the DASH and run positive and negative controls. If controls pass and without a repeat of the error, the issue is resolved.

Nuclein Customer Support

Phone: 1-888-992-DASH
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Website: www.nuclein.com

Appendix A: DASH® Rapid PCR System Specifications

PARAMETER	SPECIFICATION
Patient sample	Nasal swab tip inserted into single-use cartridge
	All required chemicals provided in cartridge
Test methodology	Completely automatic sample processing
	RT-PCR, Reverse-Transcriptase Polymerase Chain Reaction
Time to results	Run-time of 15 minutes
Data storage	16 GB
	Results available via the Cloud if enabled
	Retained through power cycles
User interface	4.3” color TFT LCD display with capacitive touch screen
Communications	10/100 Mbps Ethernet port for data transfer
	3 USB ports for barcode reader, printer USB ports communicate only with Nuclein provided accessories
Printed reports	Printer
Power supply	External power brick provided
	12 VDC 7A peak
	120 VAC 3-wire grounded power cord provided
Operating environment	Indoor use, office/laboratory
	15°C to 30°C (59F to 86°F)
	20% to 80% RH (non-condensing)
	Altitude 0 to 1,676 meters (5,500 feet)
Storage environment	5°C to 38°C 41°F to 100°F)
	5% to 85% RH (non-condensing)
Dimensions	4.3” W x 11.6” H x 15.1” D
	109 mm W x 295 mm H x 384 mm D
Weight	4.4 kg (9.7 lbs)

Appendix B: DASH® Rapid PCR System Safety and Electromagnetic Compatibility (EMC)

Safety Requirements	The DASH Rapid PCR System complies with applicable requirements of: • IEC 61010-1 Safety requirements for electrical equipment for measurement, control, and laboratory use Part 1: General requirements	
Electromagnetic Compatibility (EMC)	The DASH Rapid PCR System is designed and tested to CISPR 11 Class A and complies with the applicable emission and immunity requirements of: • IEC 60601-1-2: 2014 +A1:2020 Medical Electrical Equipment – Part 1- 2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests	
Electromagnetic Emissions	The DASH Rapid PCR System is designed and tested to the applicable requirements of: • FCC 47 CFR Part 15, Subpart B – including section 15.107 and 15.109 • FCC 47 CFR Part 15, Subpart C – including section 15.209 and 15.247	
Wireless Coexistence	The DASH Rapid PCR System is designed and tested to the applicable requirements of: • ANSI C63.27 2021 American National Standard for Evaluation of Wireless Coexistence.	
Handheld Barcode Scanner – Safety, Regulatory and Environmental Compliance	Environmental	50581:2012 RoHS 2011/65/EU (2015/863) – EN 50581:2012 IEC 63000 REACH 1907/2006
	Electrical Safety	IEC 62368-1 2nd ed. EN 62368-1:2014/AC:2015 UL/IEC 60950-1, 2nd ed. CAN/CSA C22.2 No.60950-1, 2nd ed.
	LED Safety	IEC 62471:2006 (Ed.1.0) EN 62471:2008 (LED)
	EMI-RFI	FCC 47 CFR Part 15B, ICES-003, EN55032, EN55024, EN55035, VCCI, and SABS

Appendix C: DASH® Rapid PCR System Wi-Fi Specifications

The DASH® instrument does not require a high quality of service when operating on a Wi-Fi or wired network. The instrument does not require Wi-Fi to fulfill its intended use. The optional Wi-Fi is limited to administrative and data transfer activities. Data rates of 1Mbps is sufficient.

The DASH instrument should be placed within 100 feet (30m) of a wireless access point if Wi-Fi connection is desired. Wi-Fi performance can be negatively impacted by the presence of walls, large metal structures, or radio frequency interference from other devices. In very busy environments with multiple receiver devices and transmit devices working in Bluetooth, Wi-Fi, or cellular there is the possibility that data on the DASH instrument is interrupted from an interfering transmitter. In such cases try to locate the offending source and establish distance from it (recommended a minimum of 20 cm), remove it from the vicinity, or power it off during use of the DASH instrument.

The DASH instrument transmits data via a secure and encrypted SSH link. To further ensure the security of data, it is recommended Wi-Fi connection employ a security protocol. WPA2 is supported by the DASH Instrument.

Frequency	Channel	Transmit Power
2.4GHz (2.4GHz to 2.473 GHz)	***802.11a***	
	6 Mbps	16 dBm (40mW)
	54 Mbps	15 dBm (31.6mW)
	802.11b	
	1 Mbps	16.5 dBm (44.7mW)
	11 Mbps	16.5 dBm (44.7mW)
	802.11g	
	6 Mbps	16 dBm (40mW)
	54Mbps	15.5 dBm (35.5mW)
	802.11n	
	HT20; MCS0-7	13.5 dBm (22.4mW)
	HT40; MCS0-7	13.5 dBm (22.4mW)
5 GHz (5.15GHz to 5.85 GHz)	***802.11n (5GHz)***	
	HT20; MCS0-5	16 dBm (40mW)
	HT20; MCS6-7	15 dBm (31.6mW)
	HT40; MCS0-7	13 dBm (20mW)
	802.11ac	
	VHT20; MCS0-5	16 dBm (40mW)
	VHT20; MCS6-7	15 dBm (31.6mW)
	VHT20; MCS08	13 dBm (20mW)
	VHT40; MCS0-7	13 dBm (20mW)
	VHT40; MCS8-9	11 dBm (12.6mW)
	VHT80; MCS0-7	12 dBm (15.8mW)
	VHT80; MCS8-9	11 dBm (12.6mW)

Note: *Transmit power on each channel varies per individual country regulations. All values are nominal with +/-2 dBm tolerance at room temperature. Tolerance could be up to +/-2.5dBm across operating range.*

Note:

- *HT20 – 20MHz-wide channels*
- *HT40 – 40MHz-wide channels*
- *HT80 – 80MHz-wide channels*

Revision History

Revision Date	Description of Change
January 2025	Initial commercial release.
June 2025	Included details on settings for Multi-Factor Authentication (MFA); added information on addressing a specific error code. Update on Storage Environment specifications.
May 2026	Updated to address GUI changes to the Wi-Fi password screen and to note incorrect PIN lockout feature.
September 2026	Added clarification to confirming network connectivity on the DASH and included an error seen in practice.