



DASH[®] Rapid PCR System

Training & Use

Nuclein Customer Support



Table of Contents

01	Best Practices & Warnings
02	Running Controls
03	Result Interpretation: QC Results
04	Running Patient Samples
05	Result Interpretation: Patient Results

06	Technical Assistance
07	Reordering

01 Best Practices & Warnings

01 Best Practices & Warnings

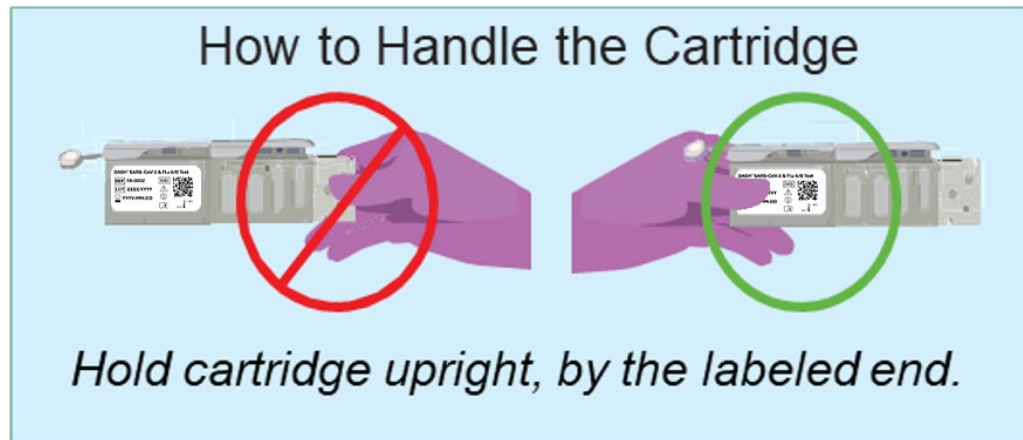
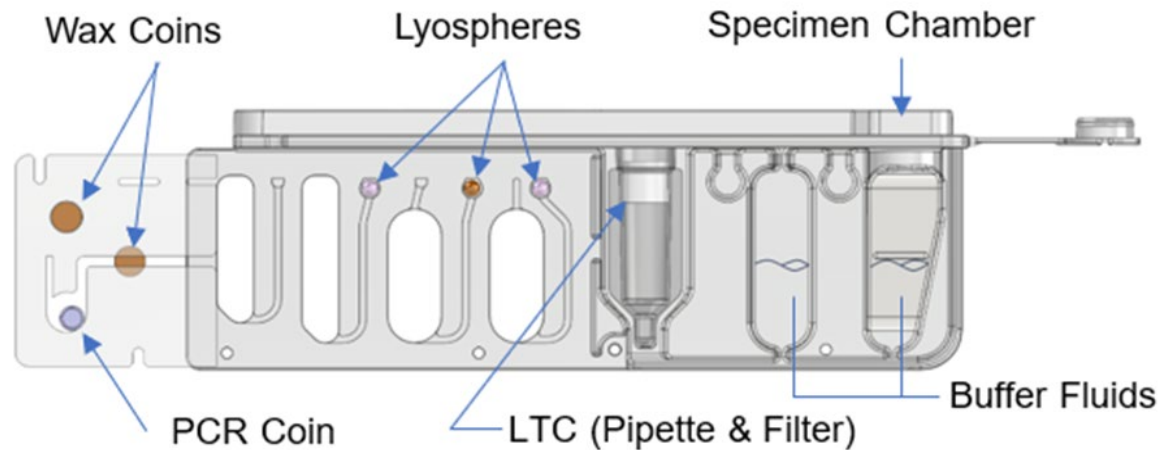
Operating the Instrument

Never move the instrument while a test is in progress.

Treat all specimens as potentially infectious.

DO NOT reuse a used test cartridge.

01 Best Practices & Warnings



Proper Cartridge Handling & Inspection

- Leave cartridge sealed until just before use.
- Always handle the cartridge by the labeled end.
 - **DO NOT** handle cartridge by the films.
 - **DO NOT** lay it on its side.
- Prior to use, inspect product for damage.
 - **DO NOT** use if packaging is damaged.
 - **DO NOT** use if it is wet or leaking
 - **DO NOT** use if it has been dropped
- Check that LTC, PCR coin, lyospheres, and wax coins are present in the cartridge.

Refer to IFU-06-022 for further guidance.

02 Running External Controls

02 Running External Controls

DASH Instrument Quality Controls

- Control swabs are external assay quality controls that monitor test performance and confirm proper function of the DASH Instrument
- Controls are for single use only
- Running External Controls are recommended:
 - With every new lot of cartridges (not shipment)
 - Each time a new operator performs a test
 - When DASH Instrument is used for the first time
 - As needed for internal quality control procedures and/or local, state, or federal regulations.

Refer to IFU-06-021 and QRG-06-002 for complete instructions

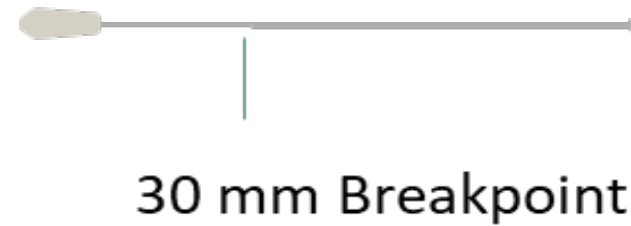


02 Running External Controls

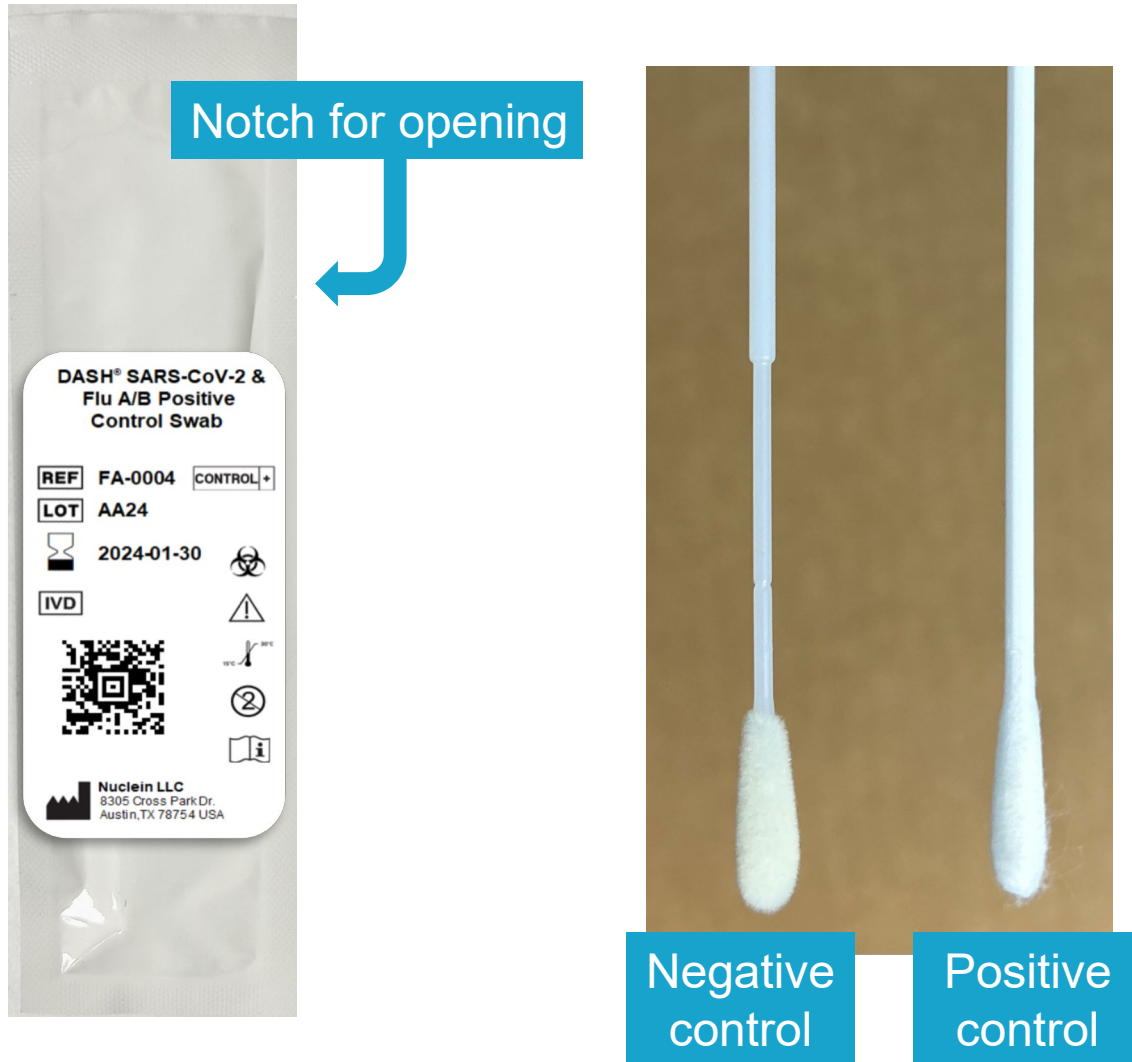
DASH® Negative Control Swab (SG-0010)

- DASH Negative Control Swabs Kit has 5 swabs per box
- Barcodes are on the control swab packaging
- Swab has a 30 mm breakpoint
- Break off the stem at the 30 mm breakpoint and close the cartridge cap on the specimen chamber

Refer to IFU-06-022 for further guidance



02 Running External Controls



DASH® SARS-CoV-2 & Flu A/B Positive Control Swab (SG-0008)

- Positive Control kit has 5 swabs individually wrapped
- Barcodes are on the control swab packaging
- Positive control swab **DOES NOT** have a breakpoint and requires extra care when breaking off the stem
 - **If the swab is broken off too high, the Specimen Chamber cap will not seal**
- Insert the swab into Specimen Chamber and then lift it up slightly, leaving about ¼" or 0.5 cm between the swab tip and bottom of the Specimen Chamber of the cartridge before bending to break

Warning: Positive control may contain biological material of human origin. Universal precautions are required when handling this product

Refer to IFU-06-022 for further guidance

02 Running External Controls

Preparing Cartridges

1. Obtain a sealed cartridge package from the DASH SARS-CoV-2 & Flu A/B Test kit (SG-0006)
 - Leave test cartridge sealed until just before use
 - **DO NOT** use if pouch is damaged or open
2. Use a DASH Negative Control Swab (SG-0010) or a DASH SARS-CoV-2 & Flu A/B Positive Control swab (SG-0008)
 - **DO NOT** reuse control swabs
3. Open the package and handle the cartridge by the labeled end.
4. Hold it upright on flat surface and peel off Cover 1
 - **DO NOT** lay it on its side
5. Insert swab

Refer to IFU-06-022 for further guidance



02 Running External Controls

Running the Test Cartridge

1. Select Username and enter PIN
2. Scan the control package barcode
3. Scan the cartridge barcode
4. Confirm swab tip is in specimen chamber and the cap is closed
5. Peel off Cover 2 and touch “Open” on the screen
6. Touch the “Seal Removed” button on the screen
7. Insert the cartridge and the test will run automatically, as the blue lights indicate the progress
8. Once the test completes, results are displayed on screen and printed

Refer to IFU-06-022 for further guidance



03 Result Interpretation: QC Results

03 Result Interpretation: QC Results

Retest

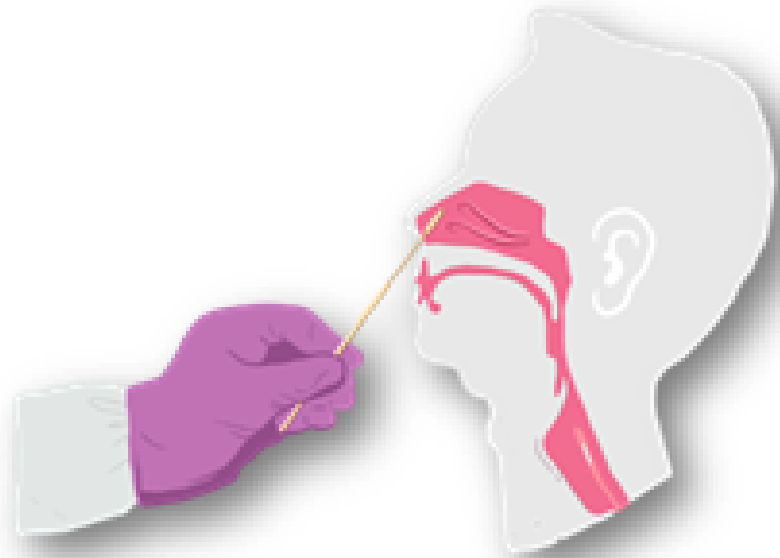
- If control results are ***“FAIL”*** or ***“Invalid”***, repeat the test using a new control swab and a new test cartridge.
- If the control test fails upon repeat testing, contact Customer Support and do not perform additional clinical tests or report results.

Refer to IFU-06-021 and QRG-06-002 for complete instructions

Control	Expected Result	Interpretation
Positive	Flu A: PASS	Flu A target RNA is detected.
	Flu B: PASS	Flu B target RNA is detected.
	SARS-CoV-2: PASS	SARS-CoV-2 target RNA is detected.
	Procedural Control: Valid	Amplification meets acceptance criteria.
Negative	Flu A: PASS	Flu A target RNA is not detected.
	Flu B: PASS	Flu B target RNA is not detected.
	SARS-CoV-2: PASS	SARS-CoV-2 target RNA is not detected.
	Procedural Control: Valid	Amplification meets acceptance criteria.

04 Running Patient Samples

04 Running Patient Samples



Sample Collection

- Use only swabs provided with the kit
- Collect patient sample, as per CDC guidance:
 1. Insert the entire collection tip of the swab (usually $\frac{1}{2}$ to $\frac{3}{4}$ of inch or 1 to 1.5 cm) inside the nostril
 2. Gently sample the nasal wall by rotating the swab in a circular motion against the nasal wall at least 4 times
 3. Take about 15 seconds to collect specimen and collect any nasal drainage that may be present in the swab
 4. Using the same swab, repeat collection with the other nostril

Refer to IFU-06-022 for complete instructions

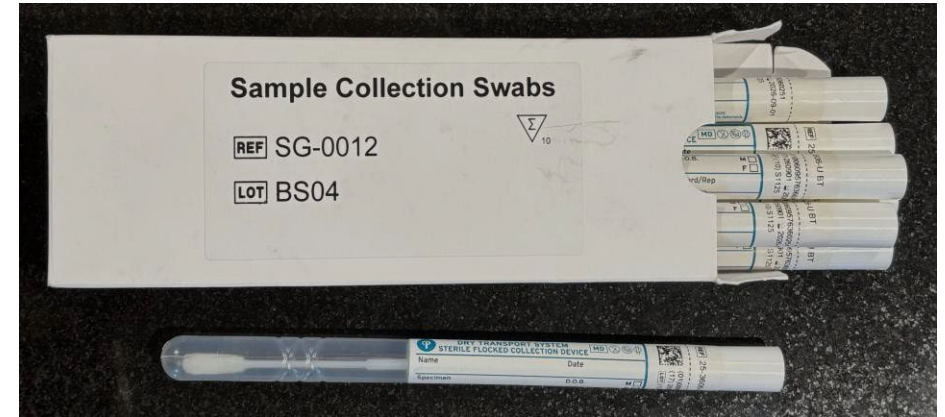
04 Running Patient Samples

Sample Stability

- Test anterior nasal swabs immediately after collection
- If delayed, insert swab into cartridge and close cap
- Run the cartridge on the DASH instrument within 1 hour of inserting the swab
- Store assembled cartridges at 15°C to 30°C only

NOTE: Do not exceed the specified storage conditions

Refer to IFU-06-022 for complete instructions



04 Running Patient Samples

Loading Sample Swab & Specimen ID

1. Remove cartridge from packaging
2. Inspect cartridge
3. On a flat surface, peel off Cover 1
4. Insert specimen swab in *Specimen Chamber*
5. Break off the stem at the 30 mm breakpoint
6. Close the cap *Specimen Chamber*
7. Scan or enter specimen ID

Refer to IFU-06-022 for complete instructions



04 Running Patient Samples

Scan Barcode or Manually Enter Specimen ID



OR

Nuclein Customer GenAdmin

Specimen ID:

Available tests

SARS-CoV-2 & Flu A/B Direct Swab-IVD

Scan specimen barcode.

Log out Settings

C08230010 Nuclein Customer F 15:08:13 02 Jun 2025

Nuclein Customer GenAdmin

Specimen ID Manual Entry

<-- Clr

A	B	C	D	E
F	G	H	I	J
K	L	M	N	O
P	Q	R	S	T
U	V	W	X	Y
Z	A-Z	a-z	0-9	\$%&

Enter Cancel

C08230010 Nuclein Customer F 15:08:13 02 Jun 2025

Scan or Enter Specimen ID:

1. Tap **Specimen ID** at the top of the GUI
2. An alpha-numeric touchscreen keyboard will appear
3. Type in Specimen ID
4. Press Enter when finished

04 Running Patient Samples

HIPAA & Sample Identifiers



Avoid using PHI such as names, social security numbers, or medical record numbers in sample identifiers



Use de-identified codes or unique identifiers that do not contain any patient-specific information

Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (1996)
Refer to page 5 of System Manual (IFU-06-023) for more information.

04 Running Patient Samples

Running the Test Cartridge

1. Scan the cartridge barcode
2. Confirm swab tip is in specimen chamber and the cap is closed
3. Peel off Cover 2 and touch “Open” on the screen
4. Touch the “Seal Removed” button on the screen
5. Gently insert the cartridge and the test will run automatically as the blue lights indicate the progress
6. Once the test completes, results are displayed on screen, printed, and uploaded into the Portal

Refer to IFU-06-022 for further guidance



Box		cight
Specimen ID:	DEB20230908_0017	
Cartridge ID:	0121S	SN: 0012
Test:	SARS-CoV-2 & Flu A/B Direct Swa	
Swab type:	Nasal with breakpoint	
Result		
Flu A: NEGATIVE		
Flu B: NEGATIVE		
SARS-CoV-2: NEGATIVE		
Procedural Control: Valid		
Test ID: A01500120905		
Start time: 08 Sep 2023 21:56:18		
Lot number: 0905 Exp: 240305		
Instrument SN: C03230013		
Touch Open to remove cartridge.		
Done		Open
C03230013		22:11:36
M2Dx		08 Sep 2023

05 Result Interpretation: Patient Results

05 Result Interpretation: Patient Results

Retest

In the case an INVALID or ERROR result occurs, repeat the test with a new cartridge and fresh sample

* If repeat test also results in an ERROR or INVALID, please contact Nuclein Customer Support at customersupport@nuclein.com or 1-888-992-DASH (3274)

TARGET	RESULT	INTERPRETATION
SARS-CoV-2	POSITIVE	The target nucleic acids of SARS-CoV-2 are detected.
	NEGATIVE	The target nucleic acids of SARS-CoV-2 are not detected.
Flu A	POSITIVE	The target nucleic acids of Flu A are detected.
	NEGATIVE	The target nucleic acids of Flu A are not detected.
Flu B	POSITIVE	The target nucleic acids of Flu B are detected.
	NEGATIVE	The target nucleic acids of Flu B are not detected.
Procedural Control	VALID	Amplification meets acceptance criteria. Test results may be reported.
	INVALID	Presence or absence of the target nucleic acids cannot be determined. Repeat test with a new cartridge.*
ERROR		Presence or absence of the target nucleic acids cannot be determined. DASH Instrument detected an error and aborted the current test. Repeat test with a new cartridge.*

Refer to IFU-06-022 for further guidance

06 Technical Assistance

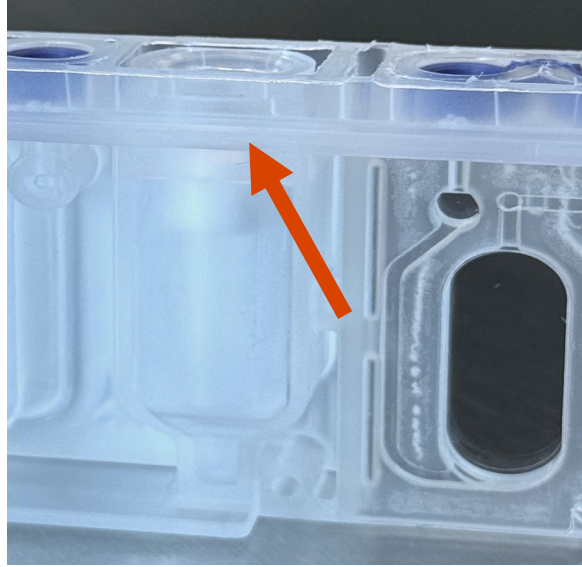
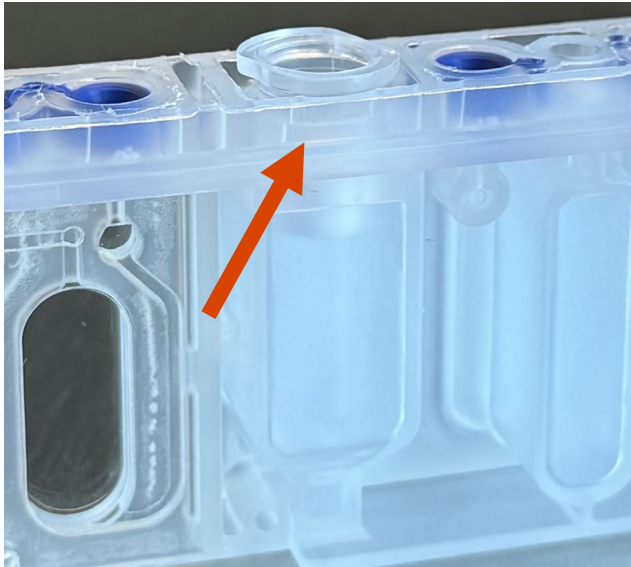
06 Technical Assistance

Warnings					
GUI Message	Cartridge was not inserted within the expected time	Cartridge was not fully inserted	Wrong cartridge was inserted (barcode did not match)	Cartridge door open too long	Cartridge was not completely removed
Action	Re-open the door of the DASH instrument and proceed with inserting the cartridge.		Re-open the door of the DASH instrument and insert correct cartridge.	Re-open the door and remove the cartridge before it times out.	
Explanation	Cartridge was not inserted within 24 seconds		Incorrect barcode was read	Cartridge was not completely removed within 24 seconds	

Please refer to IFU-06-023 for further detail.

- Operator has 24 seconds to insert and remove a cartridge
- The DASH Instrument checks the **Expiration Date** to make sure expired cartridges aren't inserted
- The DASH Instrument also checks the cartridge serial number

06 Technical Assistance



Tip Dock Errors

- Rarely seen error
- Can occur when LTC is not seated properly
- Preventable by checking the cartridge for missing or misplaced LTC

Code:

0x25000002

GUI:

Failed – tip
dock error

Action:

Verify LTC
presence and
retest if
necessary

Explanation:

Instrument didn't properly
grab the LTC
(pipette) inside the
cartridge

Please refer to IFU-06-023 for further detail.

06 Technical Assistance



Preventable Motor Error(s)

- Rarely seen error, and preventable by not forcing the cartridge into the instrument.
- Can occur when a cartridge is inserted into the instrument too aggressively
 - **Note: You only need to insert the cartridge up to the specimen chamber.**
- If the error does occur, power cycling the instrument may help clear the error.
 - If the error persists, contact Nuclein Support.

Code:

0x2301270A

GUI:

Motor controller error; Please contact service.

Action:

Remove the cartridge and power cycle the instrument to rehome motors.

Explanation:

The cartridge was inserted too forcibly, causing a motor to shift.

Please refer to IFU-06-023 for further detail.

06 Technical Assistance

Errors


Code	0x25000013	0x25000015	0 x230myyzz	0x22002xxx
GUI Message	Failed – Pressure wet filter error	Failed - Motor move encoder mismatch error	Failed - Motor error detected	Heaters failed to reach expected temperatures within the allotted time.
Action	Repeat per <i>Patient Sample Retest Procedure</i> section of the Test Instructions For Use.	Re-start the Instrument and run positive and negative controls. <ul style="list-style-type: none">• If the error returns after DASH Instrument re-start, please contact Nuclein Customer Support.• If not, issue is resolved		Ensure Instrument is being used within the parameters specified in the “Operating environment”. If within operating environment parameters, contact Nuclein Customer Support.
Explanation	Instrument experienced a pressure fluctuation due to a wet filter and aborted run.	Possible motor homing issue	Motor error: Where m = specific motor identified.	Heater error: where x = specific heaters identified.

Please refer to IFU-06-023 for further detail.

- Motor errors are usually resolved by restarting the DASH instrument
- If errors repeat, contact Nuclein Customer Support for additional service
- Retest will be necessary if a patient sample has been affected

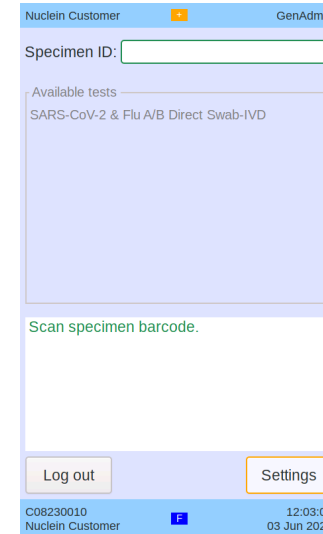
06 Technical Assistance

Over-The-Air (OTA) Software Updates

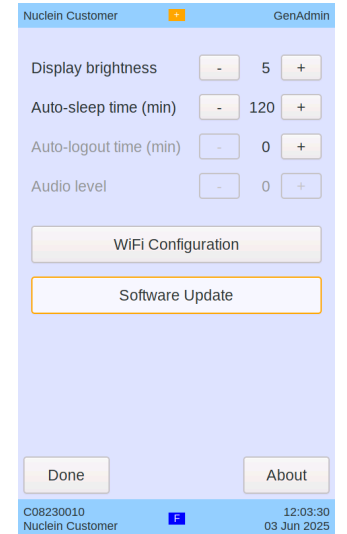
- A small orange  will appear at the top center of the GUI
- Requires connection to the customer portal through Wi-Fi or Ethernet connection
- Only Administrators will be able to perform updates
- To install the update:
 1. Tap **Settings** at the bottom of the screen
 2. Tap **Software Update**
 3. Tap **Install** to begin installation

Please refer to IFU-06-023 for further detail.

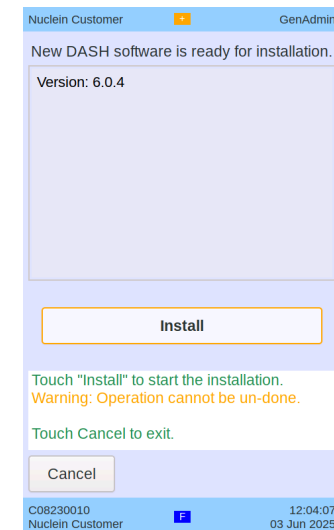
1



2



3



06 Technical Assistance



If any issues come up, before contacting Nuclein Customer Support, please collect the following information:

- Product name
- Cartridge Lot Code (LOT: XXXX-AAAA)
XXXX is the cartridge lot number
AAAA is the cartridge serial number
- Serial number of the instrument
- Error message(s) (if any)

For any questions or concerns, reach out to Nuclein Customer Support.

Telephone | US + 1.888.992.DASH (3274)

Email | customersupport@nuclein.com

Contact information for all Nuclein Customer Support offices is available on our website: www.nuclein.com

07 Reordering Supplies

07 Reordering Supplies

Test Cartridges

- Part Number: **CN-0006**
- DASH SARS-CoV-2 Flu A/B Test - 20 CS
- Quantity: 20 Cartridges + 20 Swabs

Controls

- Part Number: **CN-0008-CON**
- DASH Negative Control and DASH SARS-CoV-2 Flu AB Positive Control 5 CS
- Quantity: 5 Positive Controls + 5 Negative Controls

Additional Items

- Part Number: **CN-0012**
- DASH Additional Sample Collection Swab Kit
- Quantity: 20 swabs
- Part Number: **CN-0230**
- DASH Printer Paper
- Quantity: 4 Rolls

- Reach out to your Distributor Rep for reordering