

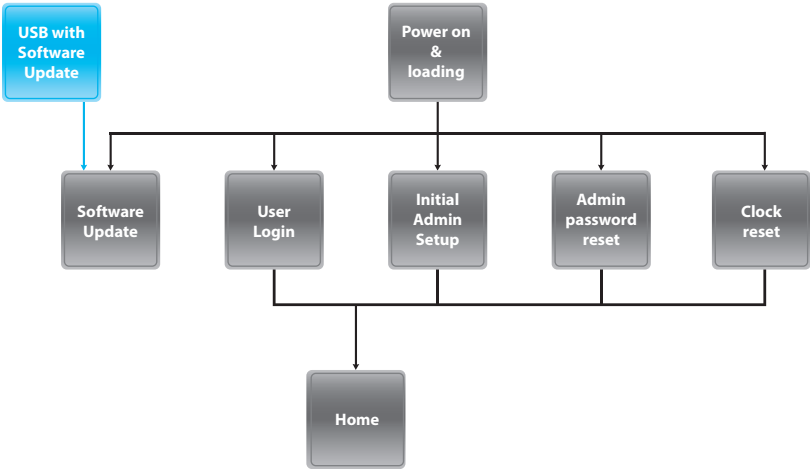
ID NOW™

INSTRUMENT USER MANUAL

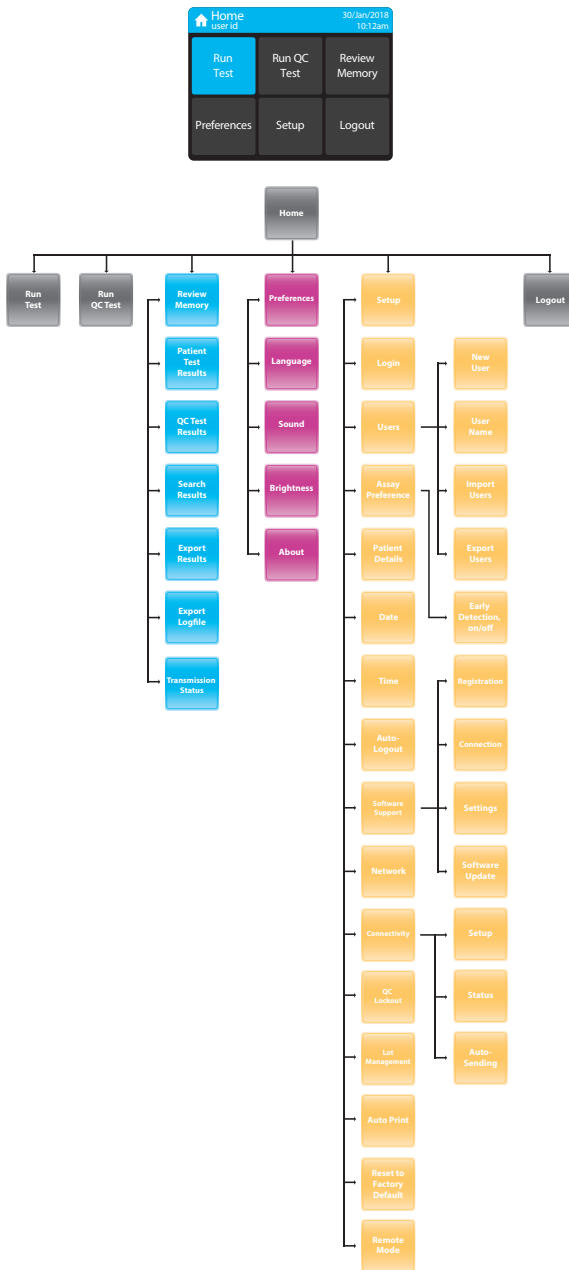
ID NOW™ Instrument User Manual



INITIAL ADMIN SETUP



HOME SCREEN MENUS



*The Connectivity Status options will only appear when the instrument has been configured by the Admin to specify the port and address of the ASTM LIS, HL7, or POCT server.

CONTENTS

Warnings and Safe Use	4
1 Introduction	6
1.1 Intended Use.....	6
1.2 Product Description.....	6
1.3 Instrument Specifications.....	7
1.3.1 Instrument.....	7
1.3.2 12V Power Supply.....	8
1.4 Unpacking.....	8
1.5 Instrument Calibration.....	8
1.6 Maintenance & Cleaning.....	9
1.7 Components.....	9
2 ID NOW™ Instrument at a Glance	10
3 Getting Started - Setup	12
3.1 Initial Setup.....	12
3.2 Instrument Status Light.....	12
3.3 User Interface.....	12
3.4 Home Screen.....	13
3.5 Navigation.....	13
3.6 Onscreen Keyboard.....	13
3.7 Admin Setup.....	14
4 Setup Menu	17
4.1 Log In (Admin Access Only).....	17
4.2 Users.....	18
4.3 Assay Preferences (Admin Access Only).....	20
4.3.1 Sample Type Selection (Admin Access Only).....	21
4.3.2 Early Detection (Admin Access Only).....	21
4.4 Patient Details (Admin Access Only).....	22
4.5 Date (Admin Access Only).....	22
4.6 Time (Admin Access Only).....	22
4.7 Auto Logout (Admin Access Only).....	23
4.8 Software Support (Admin Access Only).....	23
4.9 Network (Admin Access Only).....	26
4.10 Connectivity (Admin Access Only).....	26

4.11	Connectivity Setup Screen (Admin Access Only)	27
4.11.1	IP Address (Admin Access Only)	27
4.11.2	Port Number (Admin Access Only)	28
4.11.3	Clear Settings (Admin Access Only)	28
4.12	Status Screen	28
4.13	Auto-Sending Screen (Admin Access Only)	28
4.14	Clear Sent History (Admin Access Only)	29
4.15	QC Lockout (Admin Access Only or via POCT server)	29
4.16	Lot Management (Admin Access Only or via POCT server)	31
4.17	Auto Print (Admin Access Only)	33
4.18	Reset To Factory Default (Admin Access Only)	34
4.19	Remote Mode (Admin Access Only)	34
5	Preferences Menu	35
5.1	Language	35
5.2	Sound	35
5.3	Brightness	36
5.4	About	36
5.5	Instrument Information	36
6	Running a Test	37
6.1	User Login	37
6.2	Main Menu	38
6.3	First Time Use	38
6.4	Running A Test	38
7	Running a QC Test	40
7.1	Run QC Test	40
7.2	QC Test Results	41
8	Printing Test Results	42
9	Review Memory	43
9.1	Patient Test Results	43
9.1.1	Actions Key	45
9.2	QC Test Results	45
9.3	Search Results	46
9.4	Export Results	46
9.5	Export Logfile	47

10	Software Updates.....	48
11	Accessories	54
11.1	Universal Printer.....	54
11.2	Barcode Scanner.....	54
11.3	ID NOW™ USB Drive.....	54
12	Errors and Warnings.....	55
12.1	Errors	55
12.1.1	Power On & Loading Error	55
12.1.2	Initial Admin Setup Error	55
12.1.3	User Login Errors	56
12.1.4	Home Errors.....	58
12.1.5	Run Test / Run QC Test Errors	58
12.1.6	Printing Result Error.....	60
12.1.7	Review Memory Error	60
12.1.8	Search Results Error.....	61
12.1.9	Export Results & Export Logfile Errors	61
12.1.10	New User Errors.....	61
12.1.11	User Details Errors	62
12.1.12	Import Users Errors	63
12.1.13	Export Users Errors	63
12.1.14	Network Errors.....	63
12.1.15	Admin Password Errors	64
12.1.16	Miscellaneous Errors.....	65
12.1.17	Software Support Errors	66
12.2	Warnings	67
12.2.1	Home Warnings.....	67
12.2.2	Run Test/Run QC Test Warnings	68
12.2.3	Setup Warnings	69
12.2.4	User Warnings	69
13	Symbols.....	70
14	Ordering and Contact Information.....	72
15	Warranty	73

WARNINGS and SAFE USE

The following warnings are to be used as an aide in risk mitigation.

- ⚠ **Caution:** Use only the power supply that is provided with the instrument. Use the appropriate power supply for the region. The correct power supply is required to maintain the safety and electromagnetic compatibility of the system.
- ⚠ **Caution:** The power supply that is provided should only be used with the ID NOW Instrument.
- ⚠ **Caution:** Hot Surfaces. The Sample Receiver holder in this instrument operates at up to 60°C (140°F) and may cause contact burns or damage to materials in contact with this area.
- ⚠ **Caution:** Always operate this instrument on a clean, flat, level and stable surface not in direct sunlight. Do not drop the instrument. Ensure that air flow to the ventilation openings located on the back and base of the instrument are not restricted.
- ⚠ **Caution:** The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measure, such as relocating or re-orienting the equipment.
- ⚠ **Caution:** Never move the instrument while a test is in progress.
- ⚠ **Caution:** Follow proper infection control guidelines for handling all specimens and related items. Properly dispose of all contaminated waste according to federal, state, and local requirements.
- ⚠ **Caution:** Risk of electrical shock. Do not operate the instrument or the power supply if it has been opened, damaged or exposed to moisture, condensation or rain.
- ⚠ **Caution:** Do not disassemble or attempt to repair the ID NOW Instrument or other accessories as there is a risk of damage to the instrument. This instrument does not contain serviceable parts and should be returned for repair. Disassembling the instrument will also void the warranty.
- ⚠ **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 user manual, protection provided by the equipment will be impaired. This instrument (including power supply) is designed to operate within the manufacturer's specifications. Do not exceed the manufacturer specifications when in use.

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- ⚠ **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 mains socket outlet intended for use with ID NOW power supply should be located near the instrument and be readily accessible. Abbott recommends that cables are disconnected when not in use for an extended period.
 - ⚠ **Caution:** USB and Ethernet Interfaces. If intended for connection to external equipment, please ensure that interfaces of such equipment are separated from mains by double or reinforced insulation and present no risk of electrical shock.
 - ⚠ **Caution:** If any assay components are dropped, cracked, found to be damaged or open when received, DO NOT USE and discard.
 - ⚠ **Caution:** Due to the high sensitivity of the assays run on the instrument, contamination of the work area with previous positive samples may cause false positive results. Handle samples according to standard laboratory practices. Clean instruments and surrounding surfaces according to instructions provided in Section 1.6, Maintenance & Cleaning.
 - ⚠ **Caution:** Once reacted, the Test Base contains large amounts of amplified sample (Amplicon). Do not disassemble the Test Base and Transfer Cartridge. In the case of a positive sample this could lead to amplicon leakage and potential false positive ID NOW test results.
 - ⚠ **Caution:** To avoid contamination, do not move the ID NOW Instrument during a run or until all assay components have been removed from the instrument.

Cybersecurity Responsibilities of the Customer

As part of our assessments, we have identified risks that are dependent on how the product is fielded. The securing of the products we provide to our customers is a shared responsibility among all stakeholders. Based on the assessment conducted on ID NOW, we expect that you will take the following security steps to protect the product:

- **Physically secure the product and its operating environment:** Protect the physical security of the ID NOW instrument and operate it in a secure manner. Control and monitor physical access to the instrument using mechanisms such as security cameras, security badges, mantraps, keypads, and biometrics.
- **Securely operate and protect the product network:** Secure your network using network intrusion detection and prevention mechanisms, using adequately hardened network/application firewalls and network segmentation.
- **Limit access to authorized users:** Restrict access to ID NOW in accordance with your organization's security policies and through the user accounts maintained by the ID NOW system.
- **Manage and protect your sensitive data:** Results or other data exported from ID NOW should be controlled with appropriate laboratory practices.

1 INTRODUCTION

Rx Only

1.1 Intended Use

The ID NOW™ Instrument is a fluorescence-based instrument for the processing and analysis of ID NOW tests.

This document describes the setup, configuration and operation of the ID NOW Instrument, which utilizes isothermal nucleic acid technology for the qualitative detection of a range of infectious diseases. It is intended to aid in the diagnosis of these diseases.

1.2 Product Description

ID NOW utilizes isothermal nucleic acid amplification technology for the qualitative detection of infectious diseases. Consumables such as Test Bases and Sample Receivers are required to run each assay.

The reaction tubes in the Test Base contain the reagents required for amplification of the target nucleic acid and an internal control. ID NOW utilizes a pair of templates (similar to primers) for the specific amplification of the target nucleic acid and a fluorescently-labeled molecular beacon designed to specifically identify the amplified targets.

To perform the assay, the Sample Receiver and Test Base are inserted into the ID NOW Instrument. The sample is added to the Sample Receiver and transferred via the Transfer Cartridge to the Test Base, initiating target amplification. Heating, rotation and detection is provided by the instrument, with results automatically reported.

Additional assay specific information and work flows are detailed in the respective product inserts.

1.3 Instrument Specifications

1.3.1 Instrument

Color Touch Screen	3.5"
Communications	10/100 Mbps Ethernet Port for Data Transfer 3 x USB Ports for data export, barcode reader and printer
Data storage	999 patient test results 99 QC test results Memory allows search and retrieval Archive or export via USB
Power Supply	12V DC from external AC/DC supplied plug pack DC Voltage fluctuation: $\pm 10\%$ DC Current consumption: 12V DC, 3.0 Amps
Dimensions	8.15" W x 5.71" H x 7.64" D 207 mm W x 145 mm H x 194 mm D
Weight	3.0 kg
Operating Environment	Indoor Use 15°C to 30°C (50°F to 86°F) 10% to 80% RH (non-condensing) 0m (1.01 bar) to 2000m (0.763 bar) IP20 Type 1
Storage	15°C to 30°C (50°F to 86°F) 10% to 80% RH (non-condensing) 0m (1.01 bar) to 2000m (0.763 bar)

1.3.2 12V Power Supply

Rated input voltage:	100-240VAC
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Rated input frequency:	50/60Hz
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Rated input current:	1.2 Amps
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Operating environment:	As per instrument
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Storage environment:	As per instrument
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Output voltage:	12V
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Output current:	3.5 Amps
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1.4 Unpacking

Unpack the ID NOW Instrument and place on a clean, flat, level and stable surface within reach of an electrical outlet. The ID NOW Instrument has a carrying handle located on the back of the instrument for transport purposes. Use the carrying handle when removing the instrument from the box and when transporting short distances. Place instrument in a location where the air vents located in the back of the instrument will not be blocked. Avoid placing the instrument in direct sunlight.

Inspect for any obvious signs of damage. Report any damage immediately to Abbott. Allow the instrument to equilibrate to room temperature for at least 30 minutes.

1.5 Instrument Calibration

The ID NOW Instrument is factory calibrated and does not require any further calibration and verification.

However, if the instrument was transported or moved, a performance check using ID NOW positive and negative controls is recommended to ensure proper functionality.

1.6 Maintenance & Cleaning

The ID NOW Instrument is maintenance-free and has no serviceable parts. In the case of instrument failure or damage, contact Abbott Technical Support.

Acceptable cleaning agents include the following:

- 70% ethanol - available in commercial wipes or on a damp, lint free cloth
- 70% isopropanol - available in commercial wipes or on a damp, lint free cloth
- 10% bleach - on a damp, lint free cloth only

Do not spray or pour solution directly onto instrument when cleaning. Ensure no excess liquid is used when cleaning as it may damage the instrument.

Abbott recommends that the exterior instrument surfaces and the surfaces visible under the open lid be cleaned daily. Clean surrounding bench area. Clean instrument and surrounding areas immediately after possible patient sample contamination.

⚠ Do not disassemble the instrument for cleaning.

⚠ Do not immerse in water or cleaning solutions.

⚠ Do not clean with soap or other solutions.

1.7 Components

The following items are supplied with the ID NOW Instrument:

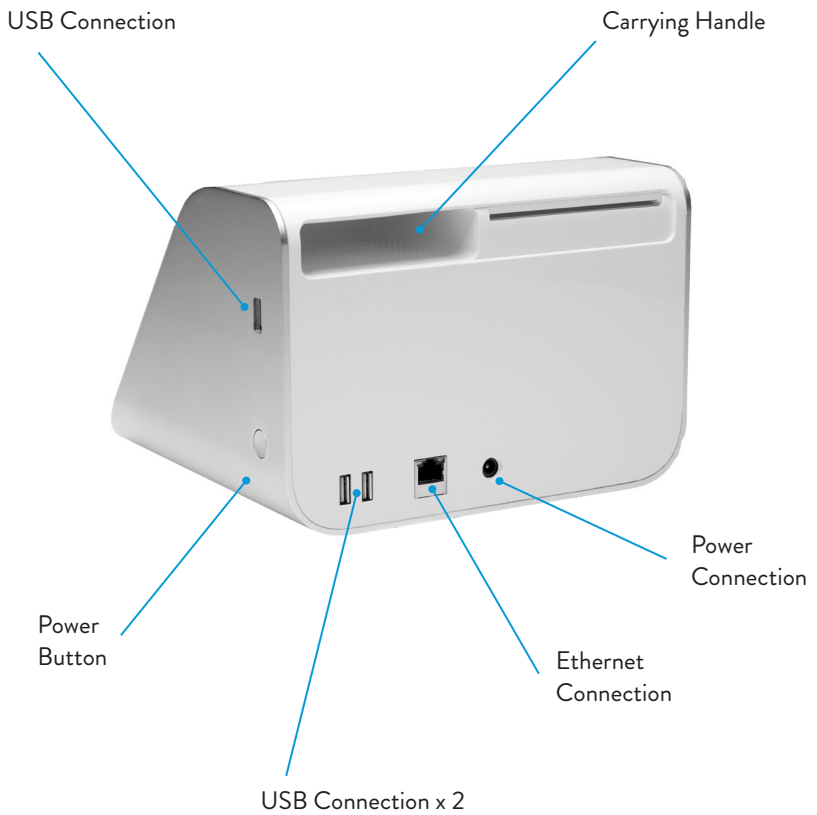
- Power Supply and Adaptor
- ID NOW Instrument User Manual
- ID NOW Instrument Quick Start Guide

2 ID NOW™ INSTRUMENT at a GLANCE

ID NOW™ Instrument, Front View



ID NOW™ Instrument, Back View



3 GETTING STARTED - SETUP

For unpacking and calibration, see Sections 1.4 and 1.5.

3.1 Initial Setup



Connect the 12V power supply to the instrument. Plug the appropriate, country specific adapter into an appropriate electrical outlet.



Power Up: Once the power is connected, press and hold the Power Button on the right side of the instrument to power up and start the instrument. Once the instrument is running, it may be turned off (shut down) by pressing and holding the Power Button for 3 seconds or longer.

If the unit is unattended for one hour, the instrument will switch to power save mode, and the screen will go black. Touch the screen to return the unit to active display operation.

3.2 Instrument Status Light

The lower right side of the front panel of the ID NOW Instrument includes a white light. This light should illuminate immediately when the instrument is powered up. The light statuses are:

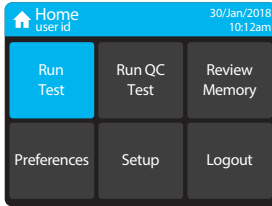
State	Indication
Slow flash	Starting up/ heaters not at temperature
On solid	Heaters at temperature
Fast flash	Software updates, Hardware fault, or shutting down

3.3 User Interface

All Operator interactions with the ID NOW Instrument are performed using the instrument touch screen.

3.4 Home Screen

Home Screen: Displays buttons for access to:

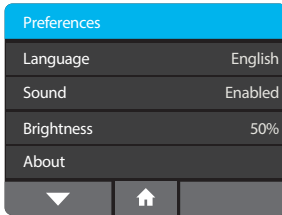


Main Menu – Home Screen

- Run Test
- Run QC Test
- Review Memory
- Preferences
- Setup (Admin Access Only)
- Logout

The current set time and date is displayed in the top right hand corner of the screen.

3.5 Navigation



Example of Navigation Bar



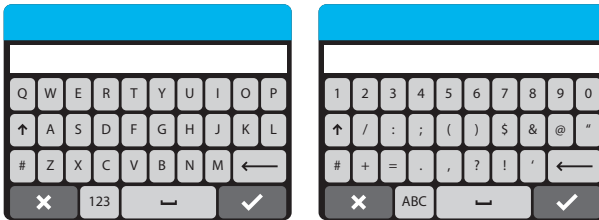
Up & Down Arrows:

Enable navigation to scroll through menus and increase/decrease setting values.

Home:

Select Home at any time to return to the Home screen.

3.6 Onscreen Keyboard



Onscreen QWERTY Keyboard & Numeric Keypad

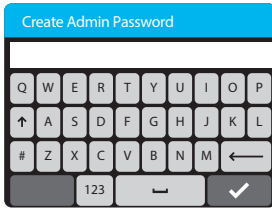
The Onscreen QWERTY Keyboard & Numeric Keypad enable user input into the ID NOW Instrument. Press '123' or 'ABC' to swap between text and number entry.

Note: Barcode input will operate at any time in these screens and can add text as if entered via the onscreen keypad.

Note: If Chinese language is selected, the Pinyin keyboard will be available. If Japanese is selected, Romaji will be available.

3.7 Admin Setup

Creating the Admin Password



The instrument requires one Admin user to be set up. The user-name is automatically set to 'Admin', but the password must be chosen.

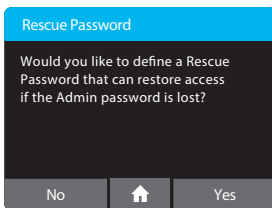
Admin User Name: *Admin*

Admin Password chosen by Admin.

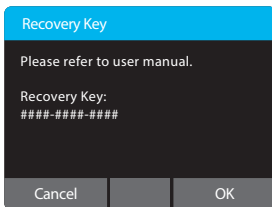
After power-up, the Create Admin Password screen will be displayed. The Admin user must type in their chosen password and press ✓.

Passwords are case-sensitive and may contain any characters on the keyboard. Passwords must be 2-20 characters.

The instrument will ask for confirmation of the password. If password is correct, press ✓ to advance to the next screen. If password is incorrect, press Cancel to return to the Create Admin Password screen.

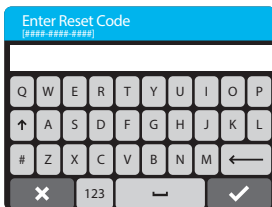


The Admin can set a rescue password in case the original is lost or forgotten.



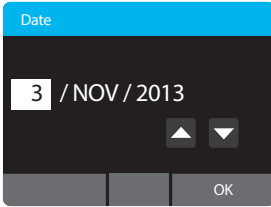
Use keyboard to enter the rescue password and reset password.

If rescue password is lost, an error screen will indicate 'Password Not Recognized'. Admin can choose 'Reset' and a Recovery Key will be automatically generated by the instrument.



Contact Abbott Technical Support with the Recovery Key. A Reset Code will be provided. Use Keyboard to enter reset code and press ✓ to advance to Enter a New Password.

Setting the Date

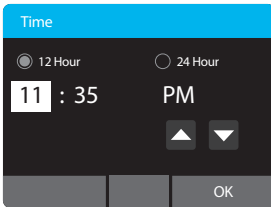


Set the correct date using the up and down arrow keys and the touch screen to move between day, month and year.

This screen will be displayed automatically following creation of Admin Password.

Press OK to advance.

Setting the Time

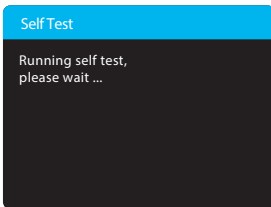


Set the correct time using the up and down arrow keys, and choose between a 12 Hour or 24 Hour display using the touch screen.

This screen will be displayed automatically once the date is set.

Press OK to advance.

Self Test

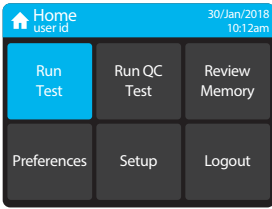


The instrument will now run a Self Test before proceeding to the **Home** screen.



If the instrument lid is open, the instrument will prompt to close the lid before running the Self Test. The Self Test will not proceed until the lid is closed.

Home



When initial set-up is complete, the **Home** screen will be displayed, with the current time and date shown in the top right, and User ID in top left corner of the screen.

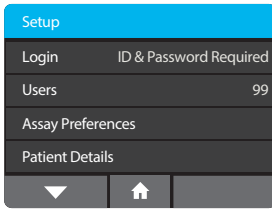
Abbott recommends that the Admin selects **Setup** to finish configuring the instrument and to add additional users. See Section 4 for details.

Alternatively, the Admin can run a test by selecting **Run Test**. When an assay is used for the first time, the user is required to run both a positive and a negative successful QC test before patient testing is allowed. See Sections 6 and 7 for details.

If not ready to continue set up or run tests, Abbott recommends that the Admin logs out by selecting **Logout**.

4 SETUP MENU

Home>Setup



The **Setup** screen allows the Admin to configure the instrument. Use the up and down arrows to scroll through menus.

Settings are saved even when power is off.

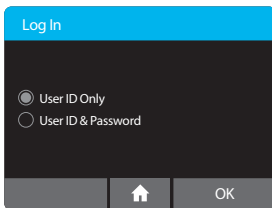
Settings include:

- Login
- Users
- Assay Preferences
- Patient Details
- Date
- Time
- Auto-logout
- Software Support
- Network
- Connectivity
- QC Lockout
- Lot Management
- Auto-Print
- Reset to Factory Default
- Remote Mode

Chosen options are displayed to the right of each setting.

4.1 Log In (Admin Access Only)

Home>Setup>Login



Log In allows the Admin to choose User ID password requirements to allow access to the instrument.

If Users do not require passwords, select 'User ID Only' and press OK. If a password is preferred, select 'User ID & Password' and press OK.

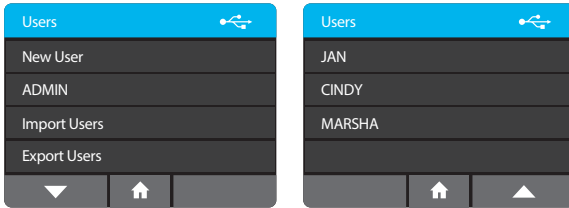
The selected option will apply to all Users with the exception of the Admin, who will always be required to use a password when logging on as 'Admin'.

If the system is changed from User ID & Password to User ID Only, existing passwords are retained in the event the Admin selects User ID & Password in the future.

If the system is changed from User ID Only to User ID & Password, user passwords are set to 'password' as a default, if a password has not been set previously for the user. The Admin can change each User's password individually, as needed.

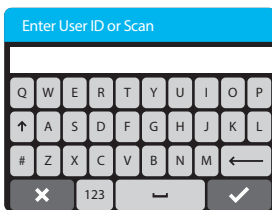
4.2 Users

Home>Setup>Users



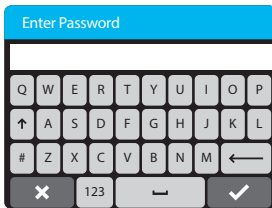
The **User Menu** allows the Admin to add, delete and edit the list of instrument users.

New User: Home>Setup>Users>New User (Admin Access Only)



Enter the User ID (for example, the User's name), or scan User ID using an electronic barcode, then press ✓.

The User ID must be 2 to 20 characters and may contain any characters on the keyboard. User IDs are not case sensitive.

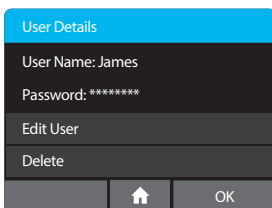


If required, the instrument will prompt Admin to enter the password and press ✓.

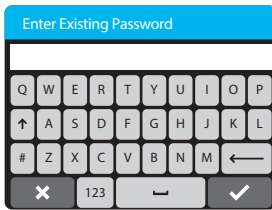
Passwords are case-sensitive and may contain any characters on the keyboard.

Note: A unique User ID is required for each user. If a duplicate User ID is entered, the instrument will prompt to use a different ID. All users may change their own password.

User Details: Home>Setup>Users

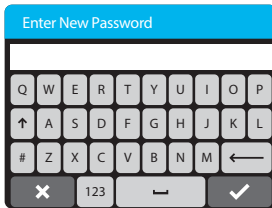


The User's password can be changed by pressing 'Edit User'.



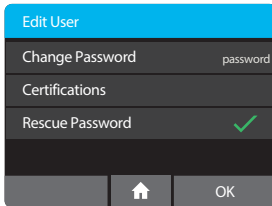
Enter existing password and press ✓.
Then enter new password and press ✓.

Passwords are case-sensitive and may contain any characters on the keyboard.



Note: If the Admin user has been selected, neither the password nor the delete button will be displayed on this screen.

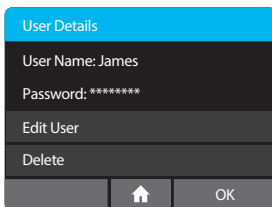
Press ✓ to return to the previous screen.



Certifications are managed by the POCT system and indicate which assays the user is certified to run. Users can use the Edit User Screen to change their password and view current Certifications. Admin will also have option to set Rescue Password.

Note: Users not managed by POCT system will not see certifications.

Deleting a User: Home>Setup>Users (Admin Access Only)



To delete a current User, press Delete.

A warning will be displayed confirming to delete user.

Press OK to delete User and return to the Setup Users screen.

Press Cancel to return to the Users screen without deleting the user.

Note: Deleting a User is permanent. Once deleted, the User profile will be lost.

Test results already stored in the instrument performed by this User will not be affected.

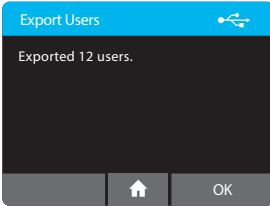
Export Users: Home>Setup>Users>Export Users



Export all configured users to a USB drive connected to the instrument.

This user list can then be imported to another ID NOW Instrument or to the same instrument following a reset to factory settings.

Press OK to return to the Users screen.



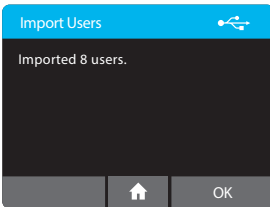
Import Users: Home>Setup>Users>Import Users



Import a complete user list that has been exported from an ID NOW Instrument, using a USB drive connected to the instrument.

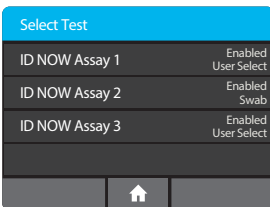
Press OK to return to the User screen.

Note: Only Users exported from an ID NOW Instrument can be imported.



4.3 Assay Preferences (Admin Access Only)

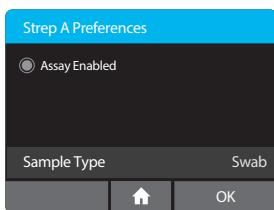
Home>Setup>Assay Preferences



The **Assay Preferences** Menu allows the Admin to enable or disable a particular assay.

The Admin can select the desired assay from the **Select Test** menu.

Home>Setup>Assay Preferences

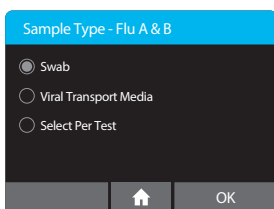


When the Assay Enabled indicator is set to on (default mode) the assay is selected and will appear on the Assay menu choice. In this example, Strep A is enabled.

4.3.1 Sample Type Selection (Admin Access Only)

Home>Setup>Assay Preferences> <Assay Name> >Sample Type

If the assay has more than one sample type available to them, the Admin will be allowed to choose the applicable sample types for that assay on the instrument.



As an example, the Influenza A & B test is shown.

If **Swab** is selected, only the swab method will be shown when running a test.

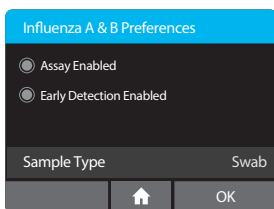
If **Viral Transport Media (VTM)** is selected, only the VTM method will be shown when running a test.

Choose **Select per Test** if the instrument is intended to run both Swabs and VTM samples. Users will be required to select the appropriate Sample Type each time they run a test.

Press OK to save the settings and return to the Setup Menu.

4.3.2 Early Detection (Admin Access Only)

Home>Setup>Assay Preferences> <Assay Name>



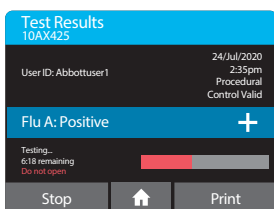
Some Assays offer an Early Detection feature:

See Influenza A & B p/n IN427000 for more details. The Early Detection feature allows a multi-target assay to end as soon as a positive result is detected in **one** of the targets. **The second target will not be reported.**

TO TURN ON EARLY DETECTION: ensure that the Early Detection Enabled box is ticked.

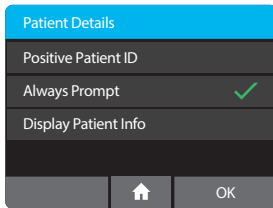
TO TURN OFF EARLY DETECTION: ensure that the Early Detection Enabled box is clear.

If Early Detection Enabled is OFF, assays with two or more targets will display a Positive result as soon as it is detected. The second target result will be pending until a Positive or Negative result is reported.



4.4 Patient Details (Admin Access Only)

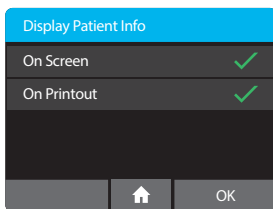
Home>Setup>Patient Details



Use the Patient Details menu option to enable a confirmation step in the Read Test workflow to verify the identity of the patient. This **Positive Patient ID** feature is only enabled when connectivity is set to POCT-1A.

Press **Always Prompt** to toggle between on (checked) and off (unchecked).

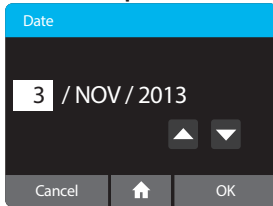
Note: The POCT server can enable/disable Positive Patient ID.



Patient Info can be displayed on Screen or on Printout by pressing **Display Patient Info** which will advance to a screen to choose **On Screen** and/or **On Printout**. Press OK to accept changes and return to Home screen.

4.5 Date (Admin Access Only)

Home>Setup>Date



The **Date** Menu allows the Admin to set the correct date.

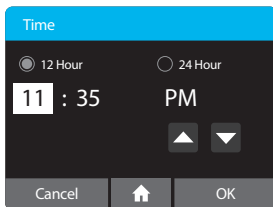
Use the up and down arrow keys and the touch screen to change the date and move between day, month and year.

Press OK to save the settings and return to the Setup Menu.

Note: The POCT server can set the date.

4.6 Time (Admin Access Only)

Home>Setup>Time



The **Time** Menu allows the Admin to set the correct time.

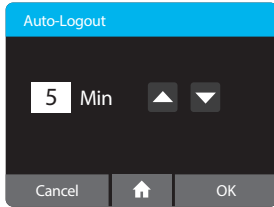
Use the up and down arrow keys and touch screen to change the time and choose between a 12 Hour or 24 Hour display.

Press OK to save the settings and return to the Setup Menu.

Note: The POCT server can set the time.

4.7 Auto Logout (Admin Access Only)

Home>Setup>Auto-Logout



The **Auto-Logout** Menu allows the Admin to select when the instrument automatically logs a User out after 5 minute and up to 60 minutes of inactivity. Use the up and down arrow keys to change **Auto-Logout** time in 5 minute intervals.

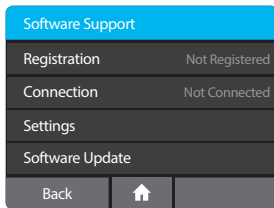
This will limit access to authorized users.

To turn feature off, scroll up from 60 Min.

Press OK to save the settings and return to the Setup Menu.

4.8 Software Support (Admin Access Only)

Home>Setup>Software Support



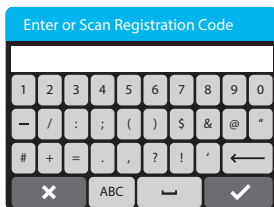
The **Software Support** Menu allows the Admin to manage instrument software updates over the network.

Press **Registration** and follow the on-screen prompts to register (or deregister if previously registered) the instrument with the Abbott Software Support Service using a Registration Code provided by Abbott.

Press **Connection** (once the instrument is registered) to test the network connection to the Abbott Software Support Service or re-establish the network connection if it has been lost.

Press **Settings** to turn on/off automatic downloading of a software update file from the Abbott Software Support Service.

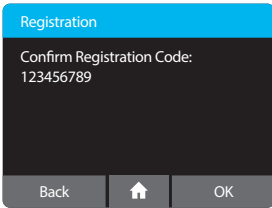
Press **Software Update** to install the software update file on the instrument.



Registration

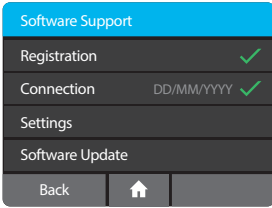
When registering the instrument with the Abbott Software Support Service, enter or scan a **Registration Code** provided by Abbott.

Contact Abbott Technical Support to request access.



Confirm the **Registration Code** or if needed correct it before proceeding.

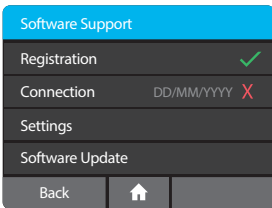
Follow the on-screen prompts to complete the registration process. (See Section 10 Software Updates).



Once the instrument successfully registers with the Abbott Software Support Service, the **Registration** changes from “Not Registered” to a green checkmark to indicate its success status.

A successful registration also changes **Connection** from “Not Connected” to a green checkmark and the connection date (DD/MM/YYYY).

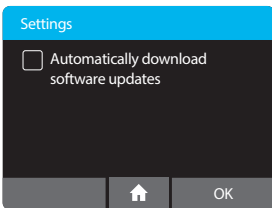
If **Connection** has a green checkmark status, the Admin can press **Connection** to test the network connection with the Abbott Software Support Service.



Connection Lost

A red X indicates the network connection has been lost between the instrument and the Abbott Software Support Service.

Press **Connection** and follow the prompts to reestablish the network connection.

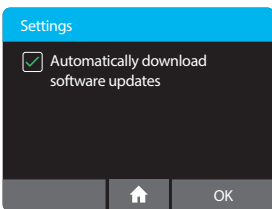


Settings

Press **Settings** to view the configurable setting.

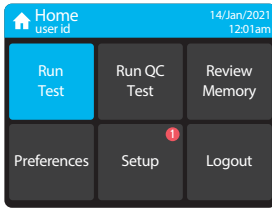
Uncheck “**Automatically download software updates**” to turn off automatic downloads.

Click **OK** to confirm the setting and return to the **Software Support** Menu.



Check “**Automatically download software updates**” to turn on automatic downloading of a software update file from the Abbott Software Support Service.

Click **OK** to confirm the setting and return to the **Software Support** Menu.



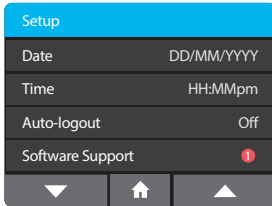
Software Update Notification

Once a software update file has been downloaded to the instrument a red circle icon displays on the following:

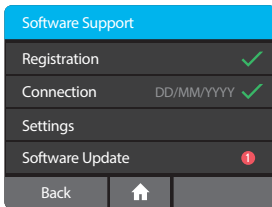
Home > Setup Menu button

Home > Setup > Software Support Menu button

Home > Setup > Software Support > Software Update button



The Admin can proceed with installing the software update.



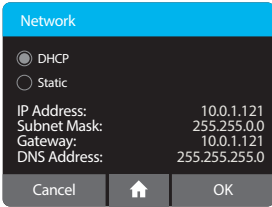
Software Installation

Click on Software Update to begin the installation process.

Follow the on-screen prompts to complete the software installation. (See Section 10 Software Updates).

4.9 Network (Admin Access Only)

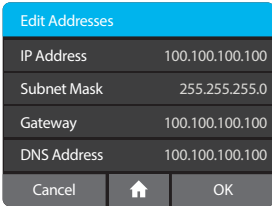
Home>Setup>Network



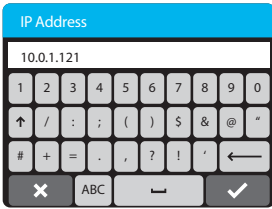
The Network menu allows the Admin to configure the network settings on the Instrument.

Functions supported include:

- Select between DHCP and Static IP address assignment.
- Configure IP Address.
- Configure Subnet Mask.
- Configure Gateway
- Configure DNS



The default is DHCP. To switch to static IP, an IP address, Subnet Mask, Gateway, or DNS Address must be entered manually using Edit Addresses screen. The details will show on right of screen, if set.



Press ✓ to save the settings and return to the Setup Menu.

Some networks require registration of a device before they are assigned an IP address. Please consult with your Network Administrator or IT Help Desk, as needed.

4.10 Connectivity (Admin Access Only)

Records may be transmitted to a Laboratory Information System (LIS) or Point of Care Data Management System (POC DMS).

Icons



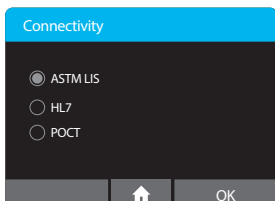
Icons appear at the upper right on certain screens when Connectivity activity occurs.

The top icon indicates an activity is in progress.

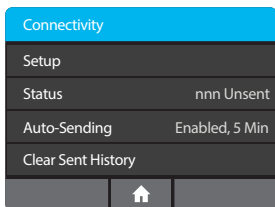
The middle icon indicates successful completion.

The bottom icon indicates an error occurred during a connectivity activity.

Home>Setup>Connectivity

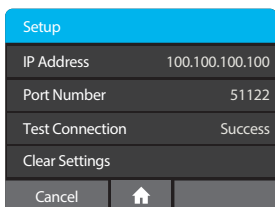


The Connectivity Menu allows the Admin to configure, edit, or control sending messages to a Laboratory Information System or the Point of Care Data Management system via the Ethernet network connection. Choose either ASTM LIS, HL7, or POCT and press OK to select.



4.11 Connectivity Setup Screen (Admin Access Only)

Home>Setup>Connectivity>Setup



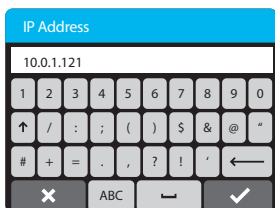
The Admin can set the IP Address and Port corresponding to the Laboratory Information System or Point of Care Data Management System.

Test Connection can be used to determine if the instrument can reach a compatible server at the configured address and port.

Changes to the IP Address and Port Number are only persisted if the user presses the OK button; Cancel will discard changes.

4.11.1 IP Address (Admin Access Only)

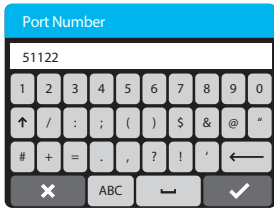
Home>Setup>Connectivity Setup>IP Address



Note: This is for entering the IP address of the LIS, HL7 or POCT server, not of the ID NOW instrument itself.

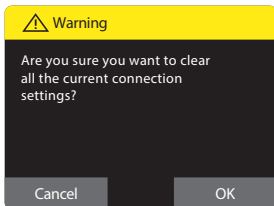
4.11.2 Port Number (Admin Access Only)

Home>Setup>Connectivity Setup>Port Number



4.11.3 Clear Settings (Admin Access Only)

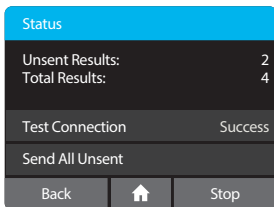
Home>Setup>Connectivity Setup>Clear Settings



Selecting OK will return connectivity IP Address and Port Number to “Not Set” and return to the Connectivity menu.

4.12 Status Screen

Home>Setup>Connectivity Status



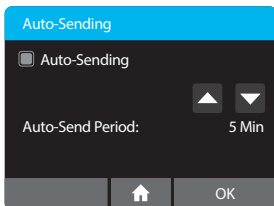
Status shows how many total records are in memory and how many have not been sent to the connectivity server. This number includes both QC test results and patient test results.

Test Connection tests connectivity to the server, as seen under Connectivity Setup.

Send All Unsent sends all records to the server that have not previously been successfully sent.

4.13 Auto-Sending Screen (Admin Access Only)

Home>Setup>Connectivity>Auto-Sending



When Auto-Sending is enabled, the instrument will regularly attempt to send all unsent records to the connectivity server at the configured period. The available selections are 5, 10, 15, or 30 Minutes, 1 Hour, and 1 Day.

Records will not be transmitted during a test.

4.14 Clear Sent History (Admin Access Only)

Home>Setup>Connectivity>Clear Sent History

Clear Sent History erases the transmission time and date record for all results sent successfully.

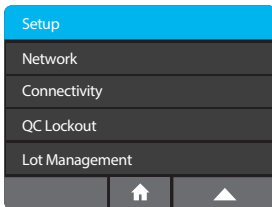
This feature may be used if switching to a new laboratory information system or if the user wants to re-transmit all test results.

4.15 QC Lockout (Admin Access Only or via POCT server)

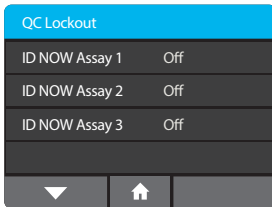
Home>Setup>QC Lockout

The Admin can enable the QC Lockout function to ensure that a QC negative and positive test must be run before patient testing is allowed on each new assay lot.

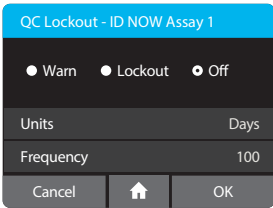
Note: When using POCT, the remote server can update these settings.



Select **QC Lockout** to configure QC Lockout options.



Select each assay from the **QC Lockout** menu to configure QC Lockout.



The **QC Lockout** Menu allows the Admin to configure QC lockout options for the assay selected.

Select **Off** to disable QC Lockout (default)

Select **Lockout** or **Warn** to prevent any patient tests being performed with a new lot until negative and positive QC has passed for that lot.

The QC Lockout function when enabled (warn or lockout mode) also allows the Admin to configure a **testing interval** for the assay chosen (**lot independent**).

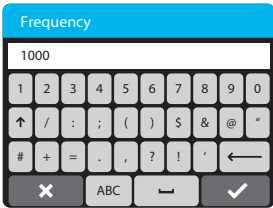
In the **Lockout** mode when the assay frequency expires, the user will be prompted to run a QC test for that particular assay before a patient test can be run.

In the **Warn** mode, when the assay frequency expires it will present the user with an option to proceed.

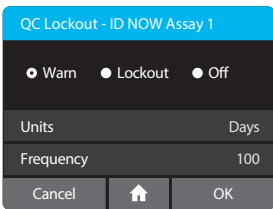
Units are set as either **days** or **number of tests** performed by pressing the units button.

Frequency can be set between 1-1000. (If **testing interval** is not required set frequency at 1000 days.)

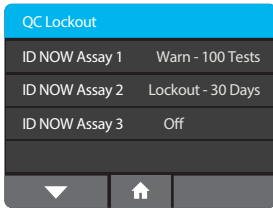
Press **Frequency** to proceed to the touchscreen keypad.



To set the Frequency enter the number of days or tests. Press X to reselect or ✓ to confirm and continue.

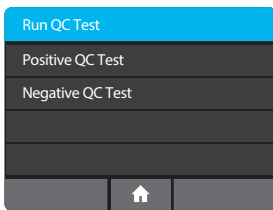


The screen will indicate selected **Units** and **Frequency**. Press Cancel to return to previous screen. When parameters are set as desired, press OK to confirm and continue.



The QC Lockout screen will provide a summary for each assay enabled on the instrument.

When the **QC Lockout** function is enabled (**warn** or **lockout**) the user will be prompted to run QC negative and positive controls before a patient test can be run. Alternatively, the user can change to a different lot (which has had a valid QC negative and positive control associated with it.)

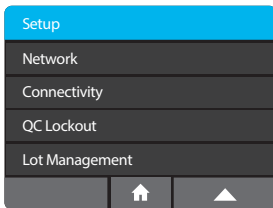


Both QC negative and QC positive tests must generate valid results before the instrument can run a patient test. Select Run QC Test and follow the steps in Section 7.

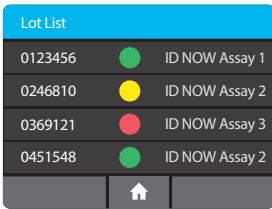
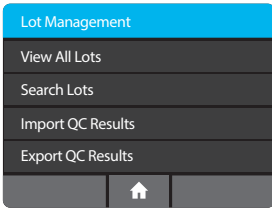
4.16 Lot Management (Admin Access Only or via POCT server)

Home>Setup>Lot Management

This feature allows the Admin to review detailed Lot information.



Select **Lot Management** to review QC test of lots on instrument as well as to **Export** and/or **Import** lots to and from instrument



Lot Management allows Admin to:

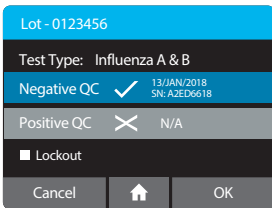
- **View All Lots** on the instrument
- **Search** for specific lots using assay, date range, or status
- **Import QC Results** onto the instrument from USB Drive
- **Export QC Results** on instrument to USB Drive

Select **View All lots** to view a list of all lots currently on the instrument. The Lot Status and Assay will be visible.

- ● Pos and Neg QC results passed
- ● Incomplete Pos or Neg QC results
- ● Pos or Neg or both QC results failed

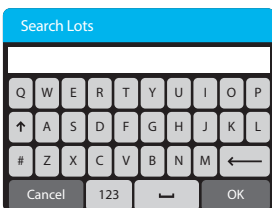
Lots will be listed chronologically from newest qualification to oldest.

Select **Search Lots** to search for a specific Lot or all Lots run for a specific assay.

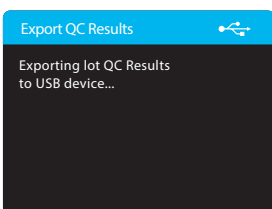


Select a lot to see its details. In this example, the Assay name as well as instrument serial number and the Date and Time of its QC runs will be displayed. The Admin has the option to **Lockout** the chosen Lot here, regardless of current status. Press Cancel to return or OK to continue.

Note: *If the lot is transmitted from POCT server, instrument serial number and date will not be present.*



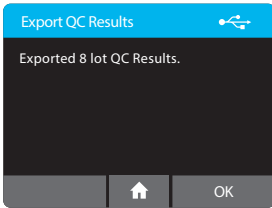
Enter **Lot number** or **Assay** name. Press OK to continue.



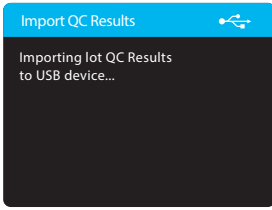
Chose **Export QC Results** to export all lots on instrument.

1. Enter USB drive
2. Select Export QC Results

This screen will appear to confirm export is in process.



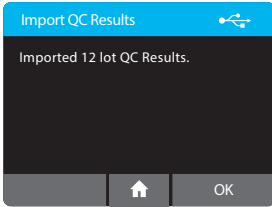
This screen confirms Export completed successfully.



Choose **Import QC Results** to import lots from a USB drive that contains exported lot files.

1. Enter USB drive
2. Select Import QC Results

This screen will appear to confirm import is in process.

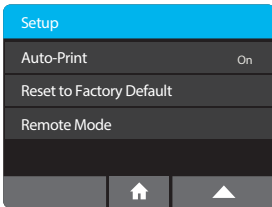


This screen confirms Import completed successfully.

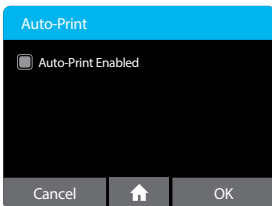
Note: For any particular lot, information on USB drive will replace information already on the instrument.

4.17 Auto Print (Admin Access Only)

Home>Setup>Auto Print



Use the Auto Print menu option to configure the instrument to print the test result immediately after running a test.

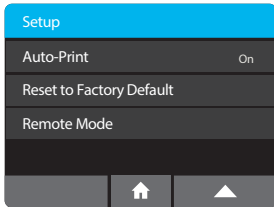


Use toggle to enable or disable Auto Print.

Click OK to continue.

4.18 Reset To Factory Default (Admin Access Only)

Home>Setup>Reset to Factory Default



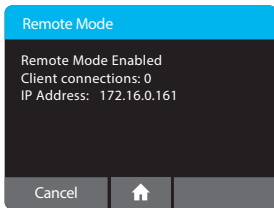
Reset to Factory Default can be accessed through the Setup screen and allows the Admin to return the instrument to the default factory settings.



Caution: This will delete all users, patient test results, and QC results from the instrument. It is recommended that any desired data be exported before performing this function.

4.19 Remote Mode (Admin Access Only)

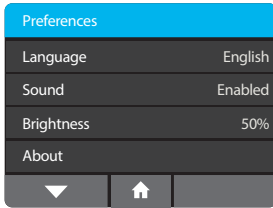
Home>Setup>Remote Mode



Remote Mode is currently not available for use by end users.

5 PREFERENCES MENU

Home>Preferences



Preferences allow the modification of the instrument settings.

Settings include:

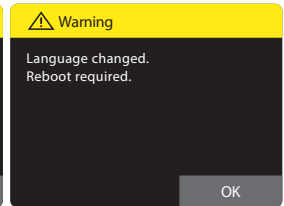
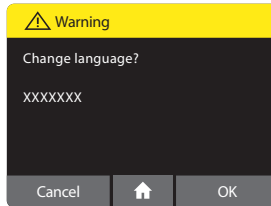
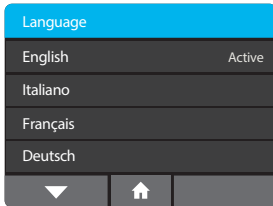
- Language
- Sound
- Brightness

The About screen displays information about the instrument.

Chosen options are displayed to the right of each setting.

5.1 Language

Home>Preferences>Language

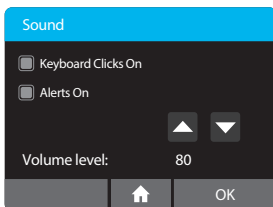


Language allows the selection of a preferred language.

Select the desired language from the list. When prompted, press OK to save the settings. The instrument will prompt to reboot the instrument for languages to take immediate effect.

5.2 Sound

Home>Preferences>Sound



The Instrument uses sound for the following functions:

- A click whenever the touch screen is used.
- Tones will sound to indicate when the instrument warm up routine is complete, when the transfer cartridge is recognized, and when the test is complete, as well as for alerts and warnings.

Keyboard clicks and alert sounds can be turned on or off by using the touch screen. Volume can be increased or decreased using the up and down arrows.

Press OK to save the settings and return to the Preferences Menu.

5.3 Brightness

Home>Preferences>Brightness

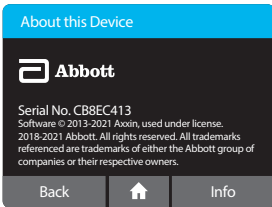


The screen brightness may be adjusted using the up and down arrows. The default and recommended setting is 50%.

Press OK to save the settings and return to the Preferences Menu.

5.4 About

Home>Preferences>About

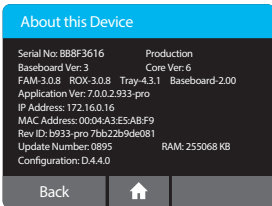


Information about the instrument is displayed here.

Press Info to display further instrument information.

5.5 Instrument Information

Home>Preferences>About>Info



The Info screen displays the following information:

- Instrument Serial Number
- Baseboard Version
- Coreboard Version
- Firmware Versions
- Application Version
- IP Address
- MAC Address
- Revision ID
- Software Update Number
- Total Memory (RAM)
- Assay Configuration

6 RUNNING a TEST

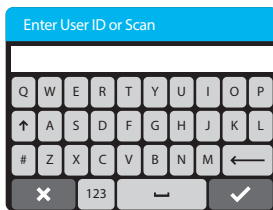


Caution: ID NOW assays may have varying CLIA Complexity levels. Please ensure the CLIA Complexity of the assay you are using is appropriate for your Laboratory.

If the instrument is being used for the first time, it must be set up by the Admin before a test can be run. For further details refer to Section 3 for Admin setup.

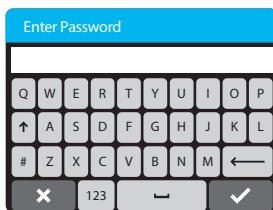
- Refer to Section 4.2 to add Users.
- Refer to Section 5.1 to select language preferences.

6.1 User Login



When the instrument is switched on, or after another User has logged out, the Enter User ID or Scan screen will be displayed.

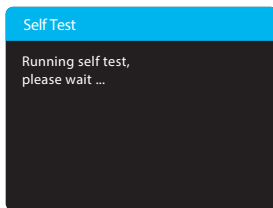
Enter the User ID, or scan using an electronic barcode reader, press ✓ to advance.



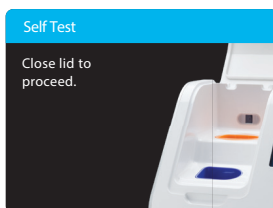
If a password is required (as specified by the Admin during Setup), a prompt will appear to enter the password. Press ✓ to advance.

The instrument will automatically perform a Self Test.

Self Test:

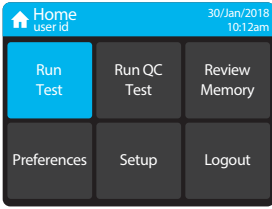


The instrument will run a Self Test before proceeding to the Home screen.



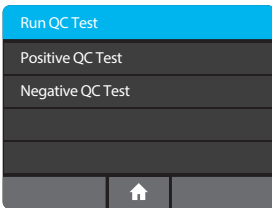
If the instrument lid is open, the instrument will prompt to close the lid before running the Self Test. The Self Test will not proceed until the lid is closed.

6.2 Main Menu



Once Self Test is complete, the **Home** screen is displayed.

6.3 First Time Use

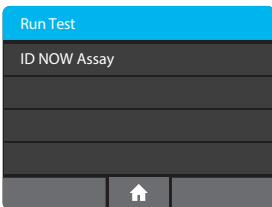
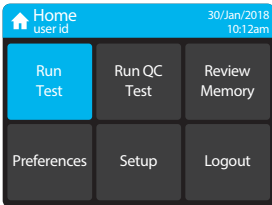


When an assay or the instrument is used for the first time the user is required to QC the instrument by running both a QC negative and QC positive external control before patient testing is allowed.

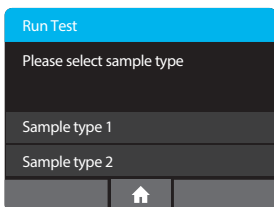
Both QC negative and QC positive tests must generate valid results before the instrument can run a patient test. Select Run QC Test and follow the steps in Section 7.

6.4 Running A Test

From the Home screen, select Run Test.

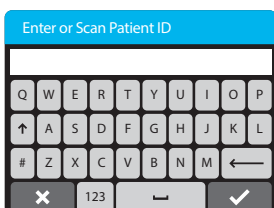


Select the **desired test** from the list of assays available. Refer to Running a Test in the assay specific ID NOW product insert for further details.



Select your sample type.

If the assay chosen has multiple sample types to choose from, the user will be prompted to select their sample type.



Enter Patient ID using on screen keyboard or barcode scanner.

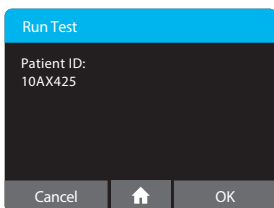
The Patient ID must be a minimum of 2 and maximum of 20 characters, is case-sensitive, and may contain any characters on the keyboard.

If the ID has been entered manually, press ✓ when complete.

If the ID has been scanned and the Patient ID is valid, if the barcode scanner is set up to automatically advance, the instrument will automatically advance to the next screen.

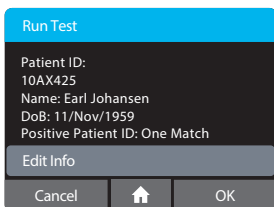
If the barcode scanner is not set up to automatically advance, press ✓.

Confirm Patient ID.



Check that the Patient ID information is correct and press OK to confirm.

If the Patient ID is not correct, press Cancel to return to the Enter Patient ID screen.



Note: If user is connected to LIS system via POCT-1A, and the Positive Patient ID is enabled, the instrument will query LIS for that patient's ID. It will return patient data to be confirmed by pressing OK. If not found, or if multiple matches are found, press Edit Info to enter Given Name, Family Name, and Date of Birth (DoB).

Note: If Always Prompt Feature is enabled, press Edit Info to advance to edit screens.



Caution: Confirmation is required as Patient ID is not editable once testing has commenced.

It is essential that the on-screen prompts are followed throughout the testing process. See specific test product inserts for further information.

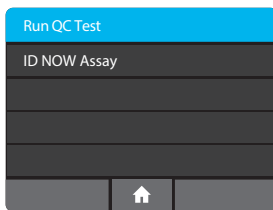
7 RUNNING a QC TEST

ID NOW test kits contain Positive and Negative External Controls. When an assay or the instrument is used for the first time, or when the software is upgraded, the User is required to run both a positive and a negative successful QC test before patient testing is allowed. See specific test product inserts for further information regarding QC test frequencies. Further controls may be tested in order to conform with local, state and/or federal regulations, accrediting groups, or the lab's standard Quality Control procedures.

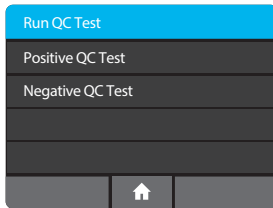
Select **Run QC Test** on the Home screen.

7.1 Run QC Test

Select the QC test to be run

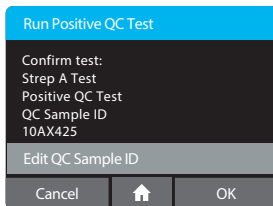


Select the desired assay from the list of available assays.



Select and confirm a Positive or Negative QC test. Confirm the test type to match the QC sample intended for testing by pressing OK and follow the on screen prompts to complete testing.

If the incorrect QC test has been selected, press Cancel to return to the QC Test Menu screen.

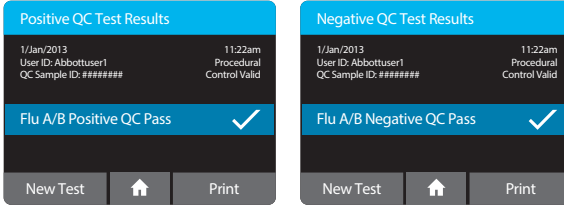


Press OK to confirm. To edit sample ID, press Edit QC Sample for optional keyboard entry.

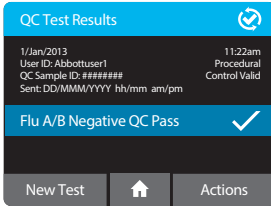
The QC test is run in the same manner as a patient test.

For QC test procedure refer to the specific test product inserts for running a test.

7.2 QC Test Results



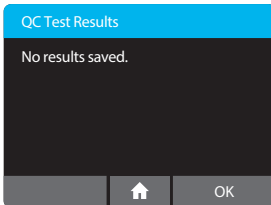
QC test results will be displayed on the screen upon test completion. These examples show positive and negative QC results for an Influenza A & B Test.



When Connectivity has been configured, the status of each result is displayed on the QC Test Results screen:

- Not Sent
- Queued for sending (as Not Sent, but Auto-Sending is enabled, which will eventually send the record)
- Connecting...
- Sending...
- Failed to send
- Failed to send, retrying...
- Sent (followed by the send date and time)

If a test result fails to transmit correctly, the instrument will attempt to send it again up to 5 additional times, with a 30 second wait between attempts.



This screen will be displayed if the instrument has not yet been used or following export and deletion of all results.

8 PRINTING TEST RESULTS

To print results, attach the Universal Printer to the ID NOW Instrument. See Section 11, Accessories, for further details and ordering information.

Influenza A & B Test
Patient ID: abcd123
Date: 12/Jul/2014
Time: 11:22 AM
Influenza A: Positive
Influenza B: Negative
Procedural Control Valid
Lot number: 0708530
Test ID: 1ef614e5-2283-43 30-a109-7df6e533b9d9
User ID: admin
Instrument serial number: BAAC7715
ID NOW

A single report for a single test of interest may be printed at the completion of a test or from the review memory screen (**Home>Review Memory**).

Attach the Universal Printer to the instrument. Select Print. The instrument will print a report on a tear-off sticker.

The ID NOW Instrument will set the default printer to the “connected” printer if only one Universal Printer is connected. If more than one printer is connected, the instrument will set the “first printer” connected printer as default.

It is recommended that the ID NOW Instrument is used with only one connected Universal Printer.

Abbott also recommends that only the Universal Printer be used with the ID NOW Instrument.

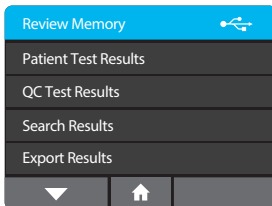
Note: *Data printed will vary depending on selections in Setup>Patient Details.*

9 REVIEW MEMORY

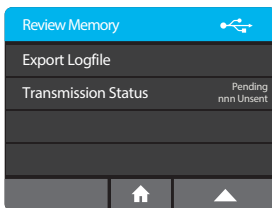
The ID NOW Instrument's memory screens enable a user to search through the stored data.

Select **Review Memory** from the Home menu screen.

Home>Review Memory



Navigate through the instrument memory by viewing a list of Patient Tests or QC Tests.

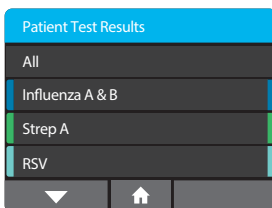


Patient and QC Test Results are exported in JSON format. A Logfile that records all the instrument actions can also be exported.

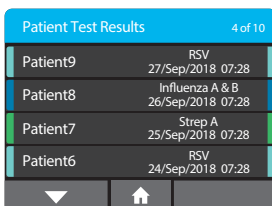
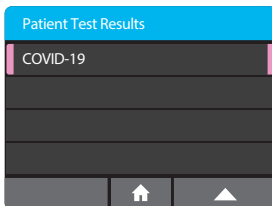
The Status selection is accessible to all users from this screen.

9.1 Patient Test Results

Home>Review Memory>Patient Test Results



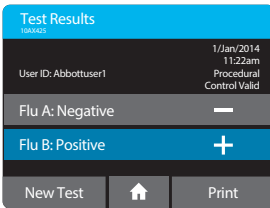
Select to choose what subset of test results to view. Selecting "All" will display all of the Patient Test Results on the instrument, whereas choosing a specific assay will display only Patient Test Results that match that assay type.



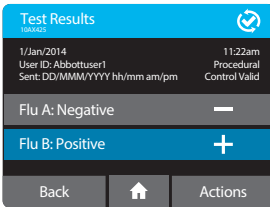
A list of all stored Patient Test Results will be displayed, showing the first 8 characters of the Patient ID. Use the up and down arrows to scroll through the list, and the touch screen to select and view a particular result.



Caution: Saved data should be archived regularly to prevent loss. See **Section 9.4, Export Results.**



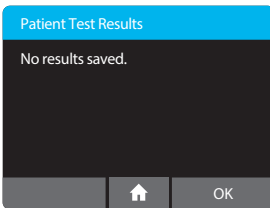
Example of a Test Result, viewed in the instrument memory.



When Connectivity has been configured, the connectivity status of each result is displayed on the Test Results screen:

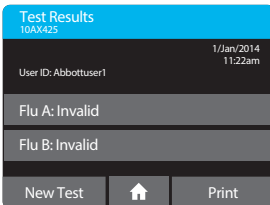
- Not Sent
- Queued for sending (as Not Sent, but Auto-Sending is enabled, which will eventually send the record)
- Connecting...
- Sending...
- Failed to send
- Failed to send, retrying...
- Sent (followed by the send date and time)

No Results Saved



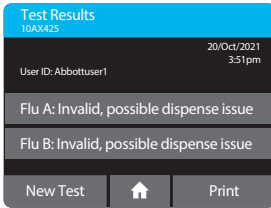
This screen will be displayed if the instrument has not yet been used for patient testing or following export and deletion of all results.

Invalid Test Results



If a test completes but the instrument failed to determine a result, the test will display an Invalid message for that result and will archive it in the instrument memory.

This example shows an Influenza A & B Invalid test result. Refer to the relevant Package Insert for further details.

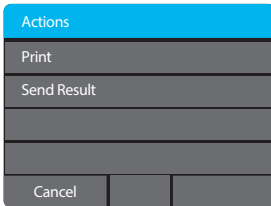


"Invalid, possible dispense issue" will display if an insufficient amount of sample was transferred to the test base.

Repeat the test using new test pieces. An invalid test may occur due to:

- Patient sample interference.
- Instrument malfunction.
- Malfunction of one or more of the test pieces.
- Insufficient amount of sample was transferred to the test base.
- Incorrect Use of Transfer Cartridge.

9.1.1 Actions Key



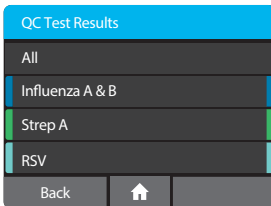
When Connectivity has been configured, instead of Print, the Actions key is displayed.

This opens the Test Actions menu, which contains Print (as before) and Send Result.

Send Result will send only the selected result. It may also be used to send a result that was previously sent.

9.2 QC Test Results

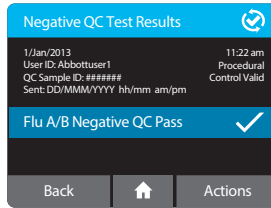
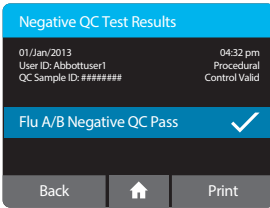
Home>Review Memory>QC Test Results



Select to choose what subset of test results to view. Selecting "All" will display all of the QC Test Results on the instrument, whereas choosing a specific assay will display only QC Test Results that match that assay type.



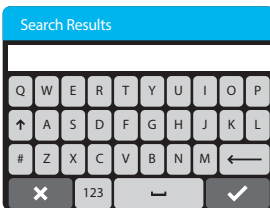
A list of all stored QC Test Results will be displayed, showing the date and time the test was run. Use the up and down arrows to scroll through the list, and the touch screen to select and view a particular result.



Examples of QC Test Results, viewed in the instrument memory.

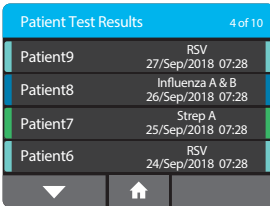
9.3 Search Results

Home>Review Memory>Search Results



Use the Search Results function to search for particular Patient Test Results.

The instrument will search Patient IDs and Date/ Times, based on the text entered.

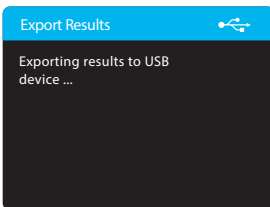


For example: Searching for the text “Sep” will return any test results where the Patient ID contains the text “Sep”, and also any test results that were obtained during the month of September.

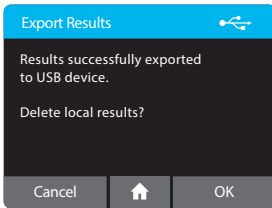
A list of results matching the search criteria will be displayed and results may be selected and viewed.

9.4 Export Results

Home>Review Memory>Export Results



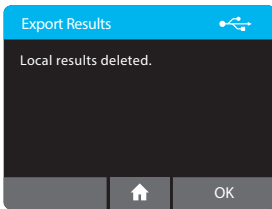
To export results, for example when the instrument memory is full, a USB drive must be inserted into one of the instrument USB ports. Individual test results are exported in JSON format. A summary of all test results on the instrument will be in CSV format.



If the ADMIN user is logged in, after successfully exporting the results, the instrument will give the option to delete all results stored in the instrument.



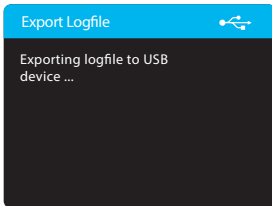
Caution: The ID NOW Instrument holds up to 999 patient results and up to 99 QC test results. A warning will appear prior to a full memory. Test and QC results must be exported before the memory is full, or memory will be overwritten.



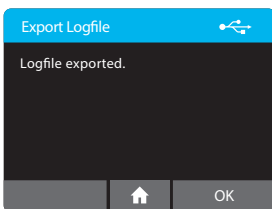
Archive saved data regularly to prevent loss.

9.5 Export Logfile

Home>Review Memory>Export Logfile



If there is an issue using the instrument, Abbott Technical Support may request to export a Logfile and email it to them. Abbott Technical Support will use the information in the log file to assist with diagnosis of the issue.



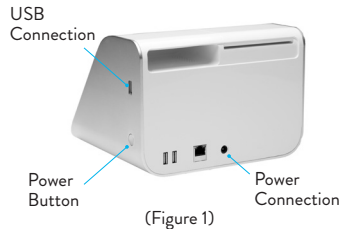
To export Logfile, a USB drive must be inserted into one of the instrument USB ports. Logfiles are not readable by users. Send log files to Abbott Technical Support to assist with instrument diagnosis.

Press OK to return to the Review Memory screen.

10 SOFTWARE UPDATES

USB Software Update:

- ⚠ **Caution:** If the ID NOW is connected [data being sent via wired (Ethernet) connection to an LIS/EMR], please make sure the data management software is on the most current version before proceeding with software upgrade of ID NOW. If you do not have a wired connection and data stored on the instrument is important, it is best practice to export the data before proceeding. The software upgrade does not delete User, Lot or Patient Results. However, there is a potential data could become corrupted and/or lost.
- ⚠ **Caution:** DO NOT REMOVE USB DRIVE DURING SOFTWARE UPDATE. USB Flash Memory Drive can be removed from the ID NOW Instrument as per the software update sequence detailed below.
- ⚠ **Caution:** Confirm all instrument settings after software update is complete.
- ⚠ **Caution:** External Quality Controls will be required on each instrument post software upgrade for all new assays utilized.
- ⚠ **Caution:** Only one USB drive may be present during the software upgrade process.



Procedure

- Step 1:** Turn the instrument OFF. Press and hold the Power Button for 3-5 seconds (Figure 1).
- Step 2:** Attach USB Flash Memory Drive containing the required software upgrade (provided) to the instrument via the **USB Connection** (Figure 1) located just above the power button on the side. Wait at least 3 seconds before proceeding to Step 3.
- Step 3:** Turn the instrument ON by pressing and holding the Power Button (Figure 1) for 3-5 seconds until the display on the screen is shown and the white LED on the front begins to blink. About 45 seconds after turning on the ID NOW, a message saying “Verifying Update” will appear.
- Step 4:** “Touch to Install” option will appear on the screen approximately 1.5 minutes after turning the instrument on. The screen must be touched to initiate the download process. **Do not remove the USB Flash Drive.**

Step 5: Select “OK”- About 8 minutes after touching the screen, the User Login screen will be displayed. **Do not log in before completing Step 6.**



Step 6: Remove power cord and USB- After the upgrade has been installed, remove the power cord from the back of the instrument (Figure 1). Remove the USB Flash Drive from the side of the instrument. Wait 10 seconds. Reconnect the power cord to the instrument.

The white LED on the front will blink a few times. Turn on the instrument. The software upgrade is complete. The USB can be used again for additional instruments.

Step 7: Now complete External Quality Controls on each instrument post software upgrade for all new assays utilized.

Note: You can verify the upgrade was successful by selecting “Preferences” button and selecting “About”, then “Info”. The software version will be displayed. See section 5.5.

Prior to running a new assay with the new software for the first time, the user is required to run a positive and negative successful QC test before patient testing is allowed. See Section 6.

If expected QC results are not obtained or you are unable to complete the software update, please contact Abbott Technical Support.

Note: Only one USB drive may be present during the software update process.

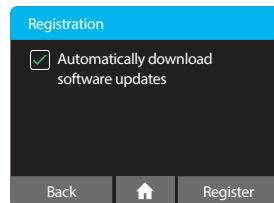
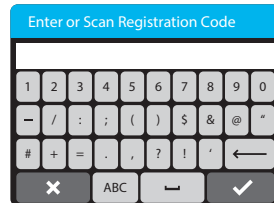
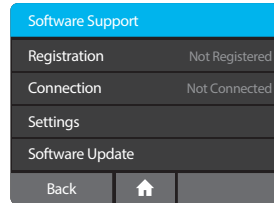
Remote Software Update

- ⚠ **Caution:** If data is being sent via a wired (Ethernet) connection to a Laboratory Information System (LIS) or Point of Care Data Management System (POC DMS), please make sure the data management software is on the most current version before proceeding with software update of ID NOW. If you do not send data to an LIS or POC DMS and data stored on the instrument is important, it is best practice to export the data before proceeding. The software update does not delete User, Lot, or Patient Results. However, there is a potential data could become corrupted and/or lost.
- ⚠ **Caution:** Confirm all instrument settings after software update is complete.
- ⚠ **Caution:** External Quality Controls will be required on each instrument post software update for all new assays utilized.
- ⚠ **Caution:** DO NOT REMOVE THE NETWORK CABLE WHEN REGISTRATING YOUR INSTRUMENT OR DURING SOFTWARE UPDATE INSTALLATION.

Procedure

Register your instrument with the Abbott server (Admin Access Only)

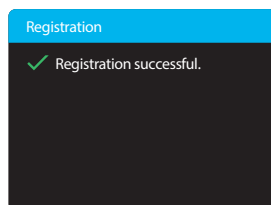
- Step 1:** Have the **Registration Code** provided by Abbott available for scanning or data entry.
- Step 2:** Navigate to **Home > Setup > Software Support**.
- Step 3:** In the **Software Support** Menu, press **Registration**.
- Step 4:** Press **Register** and then **Next** to advance.
- Step 5:** Enter or scan the **Registration Code** emailed by Abbott and press **OK (✓)**.
- Step 6:** Press **OK** to confirm the **Registration Code**.
- Step 7:** Leave the “**Automatically download software updates**” setting checked to allow a software update file to be automatically downloaded once the instrument is registered.



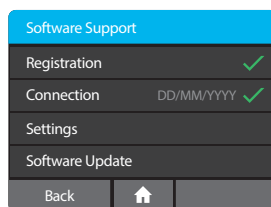
Note: If you prefer not to download software updates files currently, uncheck this setting. You can set it later by navigating to **Home > Setup > Software Support > Settings**.

Step 8: Press **Register** to send the **Registration code** to the Abbott server.

Step 9: The instrument displays “**Registration successful**” when it completes the registration task before returning to the **Software Support Menu**.

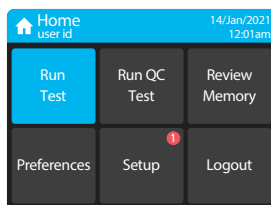


Step 10: In the **Software Support Menu**, the **Registration** status green checkmark indicates the instrument registered with the Abbott server. The **Connection Menu** displays the connection date, and a green ✓ indicates the connection to the Abbott server is good.

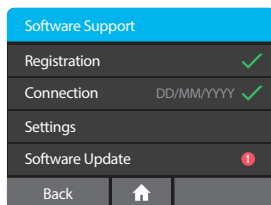


Notification of New Software Available (Admin or non-admin access)

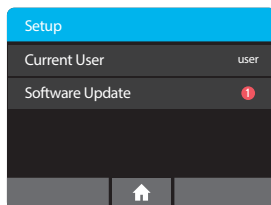
Once a software update file has been downloaded to the instrument a red circle displays on the **Setup** button on the **Home** screen.



An Admin user can check the software update file version by navigating to **Home > Setup > Software Support > Software Update**.



Non-admin users can check the software update file version by navigating to **Home > Setup > Software Update**.



Install Software Update (Admin Access Only)

A red circle on the **Setup** button on the **Home** screen, **Software Support** Menu, or **Software Update** Menu indicates an update file has been downloaded and is available for installation.

Step 1: Navigate to **Home > Setup > Software Support**.

Step 2: Press **Software Update**.

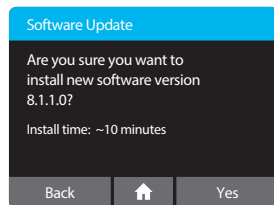
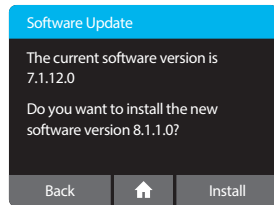
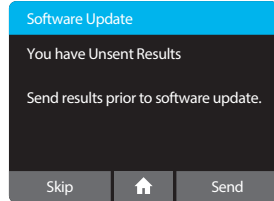
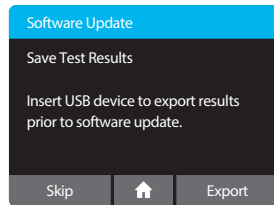
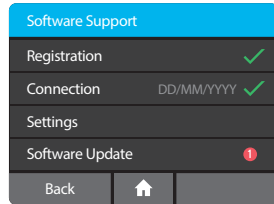
Step 3: Export or Send Results. Users with instruments not connected to a data management system can choose to **Export** saved test results to a USB device or **Skip** to advance.

Users with instruments connected to a data management system can choose to **Send** any unsent test results or **Skip** to advance.

Step 4: The current and new software version are displayed. Press **Install** to advance.

Step 5: Press **Yes** to confirm you want to install the software update.

Step 6: About 10 minutes after pressing Yes to install the software update, the User Login screen will be displayed. **Do not log in before completing Step 7.**



Step 7: After the update has been installed, remove the power cord from the back of the instrument (Figure 1). Wait 10 seconds. Reconnect the power cord to the instrument. The white LED on the front will blink a few times. Turn on the instrument. The software update is complete.

Step 8: Now complete External Quality Controls on each instrument post software upgrade for all new assays utilized.

Note: You can verify the update was successful by selecting “Preferences” button and selecting “About”, then “Info”. The software version will be displayed. See section 5.5 Instrument Information.

Prior to running a new assay with the new software for the first time, the user is required to run a positive and negative successful QC test before patient testing is allowed. See Section 6.

If expected QC results are not obtained or you are unable to complete the software update, please contact Abbott Technical Support.

11 ACCESSORIES

Accessories for use with ID NOW Instrument are available separately:

- Universal Printer
- Barcode Scanner
- ID NOW USB Drive

11.1 Universal Printer

Order Number: 55115

Replacement Sticker Roll: 26333

Data Cable: EQ005002

Refer to Universal Printer User Manual for more information. Abbott recommends using the Universal Printer with the ID NOW Instrument.

11.2 Barcode Scanner

Order Number: OPR2001ZWU1-201 or L-22X

Refer to the Barcode Scanner User Manual for more information. Only use the Barcode Scanner provided by Abbott with the ID NOW Instrument.

11.3 ID NOW™ USB Drive

Order Number: EQ004001

Abbott recommends using the ID NOW USB Drive with the ID NOW Instrument.

Alternatively, other commercially available USB Flash Memory Drives can be used. The USB must meet the following requirements:

- Formatted for FAT32, min 512 MB with only 1 partition.
- The USB Flash Memory Drive does not perform CD-ROM emulation.
- The USB Flash Memory Drive does not require proprietary software loaded to run it.

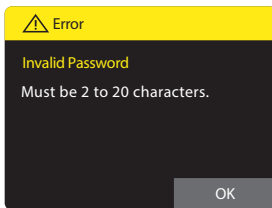
12 ERRORS and WARNINGS

This section provides troubleshooting steps for specific error and warning codes. Once the steps listed below are executed, if the error or warning persists, contact Abbott Technical Support. Contact numbers can be found at the end of the User Manual.

12.1 Errors

[**Note:** These are arranged in order of the time they may appear in the process]

Example Screen:



12.1.1 Power On & Loading Error

Error: Please Set Clock

If the internal battery fails, the instrument will lose the time and date.

Action: The Admin must log in and reset the date and time:

Home>Setup>Date; Home>Setup>Time.

If this error occurs in a subsequent power up of the instrument, there may be an on-going time and date fault.

12.1.2 Initial Admin Setup Error

Error: Invalid Password

Passwords must be 2 to 20 characters long, are case-sensitive, and may contain any characters on the keyboard.

Action: Choose a password that meets the above criteria.

12.1.3 User Login Errors

Error: User ID Not Recognized

The instrument does not recognize the User ID entered.

Action: Press OK to try again. If the error persists, the Admin must log in to check that the User ID has not been deleted. If it has, or if this is a new User, the Admin must set up the User ID:

**Home>Setup>Users or
Home>Setup>Users>New User.**

User IDs are not case sensitive.

Error: Password Not Recognized

The instrument does not recognize the password entered.

Action: Press OK to try again. If the error persists, the Admin can log in to change the password: **Home>Setup>Users.**

A Reset button is visible on Error screen only to the Admin. Admin can Press to enter Rescue Password or to retrieve the Recovery Key for Reset Code. See section 3.7.

Note: *Passwords must be 2 to 20 characters long, are case-sensitive, and may contain any characters on the keyboard.*

Error: Firmware Communications Error

The instrument cannot conduct its Self Test.

Action: Press OK to try again. If the error persists, reboot the instrument by turning it off and on again.

If this error persists, tests cannot be run on the instrument. However, stored data can be viewed: **Home>Review Memory.**

Error: Rotor Hardware Error

The instrument has failed its Self Test due to a rotor fault.

Action: Open the lid and ensure there are no consumable parts or other items blocking movements of the test rotor.

If no obstruction is found and error persists, discontinue using the instrument and contact Technical Services.

12.1.3 User Login Errors

Error: Reading Error – Empty Well

The instrument has failed the Self Test due to the empty wells having a high fluorescence reading.

Action: Ensure that the Test Base is not in the Test Base holder, and press OK to try again. If the Test Base is not present, clean the Test Base well using a swab and ethanol and press OK to try again.

If this error persists, tests cannot be run on the instrument. However, stored data can be viewed: **Home>Review Memory.**

Error: Reading Error – High Side

The instrument cannot conduct its Self Test. The instrument has failed its Self Test due to a target in the instrument not providing sufficient response.

Action: Press OK to try again, press Home to return to the Home menu. Without successfully completing Self Test the user can review results and instrument details but cannot run a test.

If this error persists, tests cannot be run on the instrument. However, stored data can be viewed: **Home>Review Memory.**

Error: Discard Pieces for Self Test

The instrument cannot conduct its Self Test if parts of the test are inside the instrument.

Action: Remove test pieces as shown under Running a Test, and press OK to try again.

If this error persists or if there are no test pieces in the instrument, check that there is not a foreign object or contamination obscuring the detector window in the bottom of the sample receiver heater block as this may be registered by the instrument as a sample receiver consumable being in place.

Press OK to try again, press Home to return to the Home menu. Without successfully completing Self Test the user can review results and instrument details but cannot run a test.

If this error persists, tests cannot be run on the instrument. However, stored data can be viewed: **Home>Review Memory.**

Error: Finish Software Update

The instrument needs to have the power connection disconnected and reconnected to complete the software update process.

Action: Disconnect the power cable from the instrument. Wait 10 seconds, then reattach the power cable. Restart the instrument.

12.1.4 Home Errors

Error: QC Test Failed

The QC test failed for the selected assay and must be repeated successfully before patient samples can be tested.

Action: Press OK to return to the Home screen and run a QC test again (**Home>Run QC Test**).

If this error persists, tests cannot be run on the instrument. However, stored data can be viewed: **Home>Review Memory**.

Error: The Last Self Test Failed

The instrument's last Self Test failed.

Action: Press OK to return to the Home screen. Log out (**Home>Logout**) and try logging in again.

If this error persists, tests cannot be run on the instrument. However, stored data can be viewed: **Home>Review Memory**.

12.1.5 Run Test / Run QC Test Errors

Error: No Configuration File Installed

A configuration file has not been installed on the instrument.

Action: Press OK to return to the Home screen. Contact Abbott Technical Services.

Error: Invalid Patient ID

Patient ID must be 2 to 20 characters long, are case-sensitive, and may contain any characters on the keyboard.

Action: Press OK to try again. If the error persists while using the barcode scanner, enter the patient ID manually.

Error: Barcode Not Recognized

The instrument has not recognized the barcode on the Test Base and cannot start the testing process.

Action: Press OK to try again. The instrument will ask to remove the Test Base. The instrument will then perform a Self Test. Once complete, try again using the same Test Base.

If the error persists, dispose of the Test Base and try a new Test Base.

Note: *The barcode on the Test Base must face the back of the instrument to be recognized.*

12.1.5 Run Test / Run QC Test Errors

Error: Timeout

The instrument has timed out during any of the steps in the testing process. More than the defined amount of time elapsed during one of the steps outlined below.

For example:

1. Between inserting the Test Base and inserting the Sample Receiver.
2. Between the completion of the warm up and the addition and confirmation of the sample
3. Between adding the sample and transferring it from the Sample Receiver to the Test Base.
4. Between transferring the sample and closing the lid.

Action: Press OK. Remove and dispose of all test pieces and repeat with a new test. Follow the on-screen instructions closely.

Error: Lid Open

The lid must not be opened during the testing process.

Action: Press OK. Remove and dispose of all test pieces and repeat with a new test.

Error: Test Expired

The test base used for Patient or QC test has expired.

Action: Press OK. Remove and dispose of all test pieces and repeat with a new test.

Error: Test Failed

The test has encountered an unrecoverable error.

Action: Press OK. Remove and dispose of all test pieces and repeat with a new test.

Error: Invalid Frequency

If the User enters a non-numeric or numerical value greater than 1000, for the QC frequency, this Error will appear.

Action: Press OK and enter a numeric value between 1 and 1000.

Error: QC Incomplete

For assays configured with QC Lockout set to **Warn** or **Lockout**, this Error will appear when a new patient test is attempted with a lot that does not have a valid QC Positive and Negative result.

Action: Select OK to stop the patient test and proceed to conduct a QC run for the lot OR the user must use a different lot of consumables for the run.

12.1.5 Run Test / Run QC Test Errors

Error: Assay Locked Out

If a **frequency** is set under **lockout** within the QC Lockout function, when the assay **Frequency** expires and a user attempts to conduct a patient test for that assay; this error message will appear.

Action: Proceed to conduct a QC run for the assay before a patient test can be run.

Error: Lot Locked Out

If the consumable lot detected has been locked out by the administrator, this error message will appear.

Action: Press OK and Contact Administrator

12.1.6 Printing Result Error

Error: Printer In Error

The instrument has not recognized the printer.

Action: If printer is not connected, connect it. If it is connected, check the printer connection and ensure it has a paper supply. Press OK to try again.

If this error persists, completely unplug the printer, reconnect to the instrument and press OK to try again.

Confirm the printer power supply is connected and the printer is turned on. Confirm printer power LED is illuminated. Confirm USB data cable is connected at the printer and the instrument.

If the problem persists, remove USB connector at the instrument, wait 10 seconds, and reconnect.

Repower the instrument and try again. The test result can be printed from the Review Memory screen.

12.1.7 Review Memory Error

Error: Test Result Not Valid

The stored result has been corrupted and cannot be viewed.

Action: Press OK to return to the list of test results.

12.1.8 Search Results Error

No Results Found.

No results have been found matching the search criteria.

Action: Press OK and try searching again using new search criteria

12.1.9 Export Results & Export Logfile Errors

Error: USB Device Not Found

The instrument has not recognized the USB drive.

Action: If a USB drive is not connected, connect it. If it is connected, check the connection. If this error persists, try using a different USB drive.

Press OK to return to the Review Memory screen.

Error: Export Failed

The export was not successful.

Action: Repeat the export process. If this error persists, try using a different USB drive.

Press OK to return to the Review Memory screen.

12.1.10 New User Errors

Error: Maximum Users Reached

A maximum of 999 users plus the Admin user can be set up.

Action: Press OK to return to the User screen to review the Users and delete Users no longer needed. This will not affect saved data.

Note: *The Admin cannot be deleted.*

Error: Invalid User ID

The User ID is in an invalid format. It must be 2 to 20 characters and may contain any characters on the keyboard. User IDs are not case sensitive.

Action: Press OK to try again. If the error persists, enter the User ID manually.

Error: User ID Already Exists

The User ID already exists.

Action: Press OK to try again. If this is a different user, assign a unique User ID.

12.1.10 New User Errors

Error: Invalid Password

Passwords must be 2 to 20 characters long, are case-sensitive, and may contain any characters on the keyboard.

Action: Press OK to try again. Choose a password that meets the above criteria.

12.1.11 User Details Errors

Error: Password Not Recognized

The instrument does not recognize the password entered.

Action: Press OK to try again. Note that passwords are case-sensitive. If error persists, the Admin can log in to change the password: **Home>Setup>Users**.

Error: Invalid Password

Passwords must be 2 to 20 characters long, are case-sensitive, and may contain any characters on the keyboard.

Action: Choose a password that meets the above criteria.

Error: Certification Expired

If user certification has expired for running an assay, this error will appear (When connected to middleware system).

Action: Contact Administrator

Note: *If connected to LIS system, user would not be included in user list.*

Error: USB Drive Not Found

The instrument has not recognized the USB drive.

Action: If a USB drive is not connected, connect it. If it is connected, check the connection.

If this error persists, use a different USB drive.

Error: Import Failed

The import was not successful.

Action: Repeat the import process. If this error persists, ensure that the USB drive contains the user list. If the error continues, try exporting the user list again from the source ID NOW Instrument, if available, and import again.

If error persists, export the list to a different USB drive and import again.

12.1.12 Import Users Errors

Error: USB Device Not Found

The instrument has not recognized the USB drive.

Action: If a USB drive is not connected, connect it. If it is connected, check the connection.

If this error persists, use a different USB drive.

Error: Import Failed

The import was not successful.

Action: Repeat the import process. If this error persists, ensure that the USB drive contains the user list. If the error continues, try exporting the user list again from the source ID NOW Instrument, if available, and import again.

If error persists, export the list to a different USB drive and import again.

12.1.13 Export Users Errors

Error: USB Drive Not Found

The instrument has not recognized the USB drive.

Action: If a USB drive is not connected, connect it now. If it is connected, check the connection.

If this error persists, use a different USB drive.

Error: Export Failed

The export was not successful.

Action: Repeat the export process. If this error persists, ensure that the USB device has available memory.

If the error persists, use a different USB drive.

12.1.14 Network Errors

Error: IP Address Invalid

The instrument does not recognize the IP Address entered.

Action: Press OK to try again. The IP Address must consist of four sets of numbers, separated by "." (i.e. 111.222.333.444).

If this error persists, contact your Network Administrator or IT Help Desk to ensure that the IP Address is correct. Press Cancel to return to the User Settings screen or Home to return to the Home screen.

12.1.14 Network Errors

Error: Subnet Mask Invalid

The instrument does not recognize the Subnet Mask entered.

Action: Press OK to try again. The Subnet Mask must consist of four sets of numbers, separated by “.” (i.e. 111.222.333.444).

If this error persists, contact your Network Administrator or IT Help Desk to ensure that the Subnet Mask is correct. Press Cancel to return to the User Settings screen or Home to return to the Home screen.

Error: Network Error

The instrument encountered a network error while trying to apply settings.

Action: Select OK and the instrument will try again.

Check the network connection, and apply the changes again. If the error persists, reboot the instrument by turning it off and then on again, and attempt the changes again.

Error: Port Number Invalid

Valid ports are whole numbers between 1 and 65535, as configured and appropriate to the laboratory information system.

Action: Use a valid port number meeting the criteria described above.

12.1.15 Admin Password Errors

Error: User ID Not Recognized

The instrument does not recognize the Admin ID entered.

Action: Press OK to try again. Ensure that the correct ID was entered. Admin ID: Admin.

Error: Invalid Password

Passwords must be 2 to 20 characters long, are case-sensitive, and may contain any characters on the keyboard..

Action: Choose a password that meets the above criteria.

12.1.16 Miscellaneous Errors

Error: Critical Error

The software has encountered a critical error and the application can only restart to recover.

Action: Press OK to reboot the instrument

Error: Temperature Out of Range

The heater temperature is not at the required temperature to perform a test.

Action: Make sure that the lid is closed and wait 5 minutes for the heater to warm the sample receiver and test base receiver. Repeat the test. If the error persists, reboot the instrument by turning it off and then on again.

Error: Hardware Timeout

The instrument hardware encountered an internal hardware response error.

Action: Repeat the test. If the error persists, reboot the instrument by turning it off and then on again.

Error: Configuration file cannot be installed

There was an error during the installation of a software update.

Action: Power off the instrument, insert the USB containing the software update, power the instrument back on.

If the issue persists, contact Abbott Technical Services to obtain the latest version of software.

12.1.17 Software Support Errors

Error: Invalid Registration Code

The Abbott provided Registration Code is not 9 digits in length.

Action: Press OK and enter the 9-digit Registration Code provided.

If the issue persists, contact Abbott Technical Services.

Error: Network cable not detected

The instrument did not detect the presence of a network cable.

Action: Plug a network cable into the Ethernet connection port and press Recheck.

Error: Check network settings

The instrument does not have static IP addresses configured.

Action: Press Settings to advance to the Network menu.

Error: Registration failed

The Registration process failed.

Action: Contact Abbott Technical Services.

Error: Unable to connect to the server

The instrument could not communicate with the external software support server while registering the instrument, testing the server connection, or reestablishing the server connection.

Action: If registering the instrument, press Retry to begin the registration process again. If testing the connection, or reestablishing the connection, press Retry to immediately retest or reestablish the connection.

If the issue persists, contact Abbott Technical Services.

Error: Registration Code expired

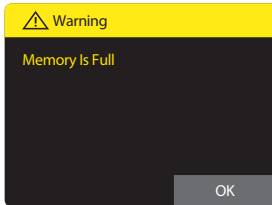
The Abbott provided Registration Code has expired.

Action: Contact Abbott Technical Services.

12.2 Warnings

[**Note:** These are arranged in order of the time they may appear in the process]

Example Screen:



12.2.1 Home Warnings

Warning: Memory Almost Full

The instrument can run only 50 more patient tests or 9 more QC tests before the memory is full.

Action: Press OK to continue to run the current test. With each additional test or QC test carried out, a similar error will be displayed showing the number of tests remaining. The Admin must export the stored test results before the memory is full, or results will be overwritten. See Section 9.4, Export Results.

Warning: Memory Is Full

The instrument can store up to 999 patient test and 99 QC results, and is now full.

Action: To avoid overwriting stored data, the Admin must export the data. See Section 9.4, Export Results.

Alternatively, Press OK to continue to run the current test.

Note that this will overwrite stored data.

Warning: Heater Not At Temperature

The instrument has not yet reached the required temperature.

Action: Press OK to return to the Home screen and wait for the white light on the front of the instrument to stop flashing before trying again.

If the error persists, power off the instrument, disconnect the DC power input connector, wait 10 seconds, reconnect and turn on the instrument. When the white light on the front of the instrument stops flashing, try again.

If this error persists, tests cannot be run on the instrument. However, the stored data can still be viewed: **Home>Review Memory.**

12.2.2 Run Test/Run QC Test Warnings

Warning: Incorrect Test Type

A test base was inserted that does not match the test type initially selected from the menu.

Action: The test must be restarted. Remove the test base and close the lid to allow the instrument to perform a self test. Restart the test, as desired.

Warning: Stop Test

The Home button was pressed during testing. Testing cannot be stopped and then resumed after one or more test pieces have been placed in the instrument.

Action: To continue testing, press Cancel. The timeouts will continue counting even with this screen displayed.

To cancel the test, press OK. Remove and dispose of all test pieces.

Warning: QC Frequency Exceeded

If a **frequency** is set under **warn** within the QC Lockout function, when the assay **Frequency** expires and a user attempts to conduct a patient test for that assay; this warning message will appear.

Action: Select OK to proceed with the run or select Cancel to stop the patient test and proceed to conduct a QC run for the assay.

Warning: QC Frequency Low

For all assays; this warning message will appear when the **testing interval** has been configured and the number of days remaining has either reached 3 (unit set to days) or when number of tests remaining is at 10%.

Action: Select OK to proceed with the run or select Cancel to stop the current patient test and proceed to conduct a QC run for the assay.

12.2.3 Setup Warnings

Warning: Reboot Required

This Warning will display in the Connectivity sub-menu when switching between Connectivity protocol types.

Warning: Reset Factory Default

If the instrument is reset to factory default settings, all Users, patient and QC results, preferences and chosen settings, including language, will be lost.

The instrument will start up as it did when first received from the manufacturer, and can be reconfigured by the Admin.

Abbott suggests exporting all user, patient and QC results to a USB drive prior to resetting to factory default.

Press Cancel to return to the Setup menu. Press OK to reset to factory default.

12.2.4 User Warnings

Warning: Delete User

If a User is deleted, all data associated with the User will be lost. However, stored data files will not be affected.

Action: Press OK to permanently delete the user. Press Cancel to return to the Setup Users screen

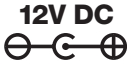
13 SYMBOLS



USB 2.0 High Speed interface connector



Wired Ethernet, 10/100 Mb/s connector



DC Power connector, for connection with supplied external. Power Supply and Adaptor. 12VDC, 3.0 Amp maximum



Hot Surface



Biological Hazard



Caution, consult accompanying documents



Restriction of Hazardous Substances Compliant



Waste Electrical and Electronic Equipment Directive Compliant



Serial Number



In Vitro Diagnostics

R_x Only

Prescription only



Manufacturer



On-Off Power Button

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.

This equipment complies with the following Emissions and Immunity standards: IEC/CISPR 11:2009+A1:2010 Class A, EN/IEC 61000-3, 3-2 Class A, 4-2, 4-3, 4-4, 4-5, 4-6, 4-8 and 4-11.

Information on Disposal for Users of WEEE

The WEEE symbol means that this product complies with the Waste Electrical and Electronic Equipment (WEEE) Directive, and used electrical and electronic equipment should not be mixed with general waste. For proper treatment, recovery and recycling, please take this product(s) to designated collection points where it will be accepted free of charge.

Disposing of this product correctly will help save valuable resources and prevent any potential negative effects on human health and the environment, which could otherwise arise from inappropriate waste handling. Please contact your local authority for further details of your nearest designated collection point. Penalties may be applicable for incorrect disposal of this waste, in accordance with your national legislation.

For users in the European Union

If you wish to discard electrical and electronic equipment (EEE), please contact your dealer or supplier for further information.

For disposal in countries outside of the European Union

The WEEE symbol is only valid in the European Union (EU). If you wish to discard this product please contact your local authorities or dealer and ask for the correct method of disposal.

14 ORDERING and CONTACT INFORMATION

Reorder numbers:

#NAT-024: ID NOW Instrument

+1 877 441 7440

Technical Support Advice Line

Further information can be obtained from your distributor, or by contacting Technical Support on:

USA

+1 855 731 2288

ts.scr@abbott.com

Africa, Russia, CIS

+44 161 483 9032

EMEproductsupport@abbott.com

Asia Pacific

+61 7 3363 7711

APproductsupport@abbott.com

Canada

+1 800 818 8335

CANproductsupport@abbott.com

Europe & Middle East

+44 161 483 9032

EMEproductsupport@abbott.com

Latin America

+57 (1) 4824033

LAproductsupport@abbott.com

15 WARRANTY

Warranty

Limited 2 Year Warranty

Use of the ID NOW Instrument

The ID NOW Instrument is a fluorescence-based instrument for the processing and analysis of ID NOW tests utilizing isothermal nucleic acid amplification technology for the qualitative detection of infectious diseases. Proper adherence to the instructions in the User Manual and package insert are critical to proper operation.

WARNING: Failure to comply with the User Manual could lead to inaccurate results.

Limited Warranty


Manufacturer guarantees to the original purchaser of the Instrument that the Instrument is free from material defects for two years from the date of purchase. This warranty does not guarantee the uninterrupted operation of the Instrument. Manufacturer's only liability and Purchaser's exclusive remedy under this warranty is that during the warranty period Manufacturer shall replace or repair, at no charge, and at the Manufacturer's sole discretion, any Instrument with a defective component. MANUFACTURER MAKES NO OTHER WARRANTIES AND EXPRESSLY EXCLUDES ANY IMPLIED WARRANTY OF MERCHANTABILITY, NONINFRINGEMENT OR FITNESS FOR A PARTICULAR USE.

There are no user-serviceable parts in the Instrument. Tampering with any portion of the Instrument, abusing the Instrument or using the Instrument in a manner inconsistent with its User Manual will void this warranty. This warranty does not apply to any component that is damaged by improper storage in environmental conditions outside the recommended range, accident, or that is subject to alteration, misuse, tampering or abuse. Purchaser must file a warranty claim in writing and within the applicable warranty period to the Manufacturer.

Please contact Technical Support prior to returning any defective components. Refer to Ordering and Contact Information section of the User Manual for additional information.

MANUFACTURER'S ENTIRE LIABILITY IN CONNECTION WITH THE INSTRUMENT, REGARDLESS OF THE LEGAL OR EQUITABLE BASIS OF ANY CLAIM, IS LIMITED TO THE PURCHASE PRICE OF THE INSTRUMENT. IN NO EVENT WILL MANUFACTURER BE LIABLE FOR ANY INCIDENTAL, INDIRECT, SPECIAL, CONSEQUENTIAL, OR PUNITIVE LOSS OR DAMAGES IN ANY WAY RELATED TO THE INSTRUMENT, OR ANY THIRD PARTY CLAIMS, EVEN IF MANUFACTURER OR ITS DISTRIBUTORS ARE AWARE OF THE POSSIBILITY OF SUCH CLAIM OR DAMAGES AND NOTWITHSTANDING THE ESSENTIAL PURPOSE OF ANY REMEDY.



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Instrument User Manual (US)

Size:
5.5 in. x 8.5 in

Printed Colors



CMYK

**Incoming Inspection Colors
(For Reference Only)**
Colors below are not used for printing



PMS 2995 U
Primary Blue

PMS 303 U
Dark Blue

PN: INNAT024
Rev: 11

Date of Last Revision:
11.7 2022/03/08