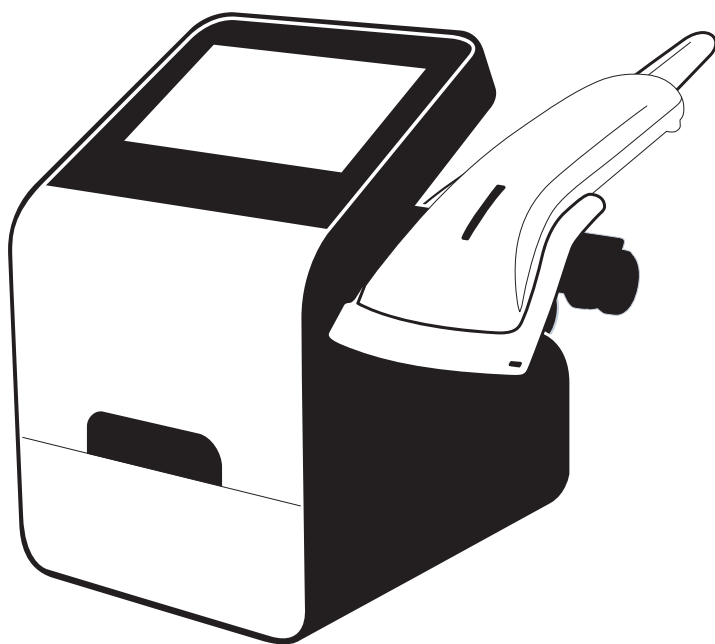




Abbott



DIGIVAL™

USER MANUAL

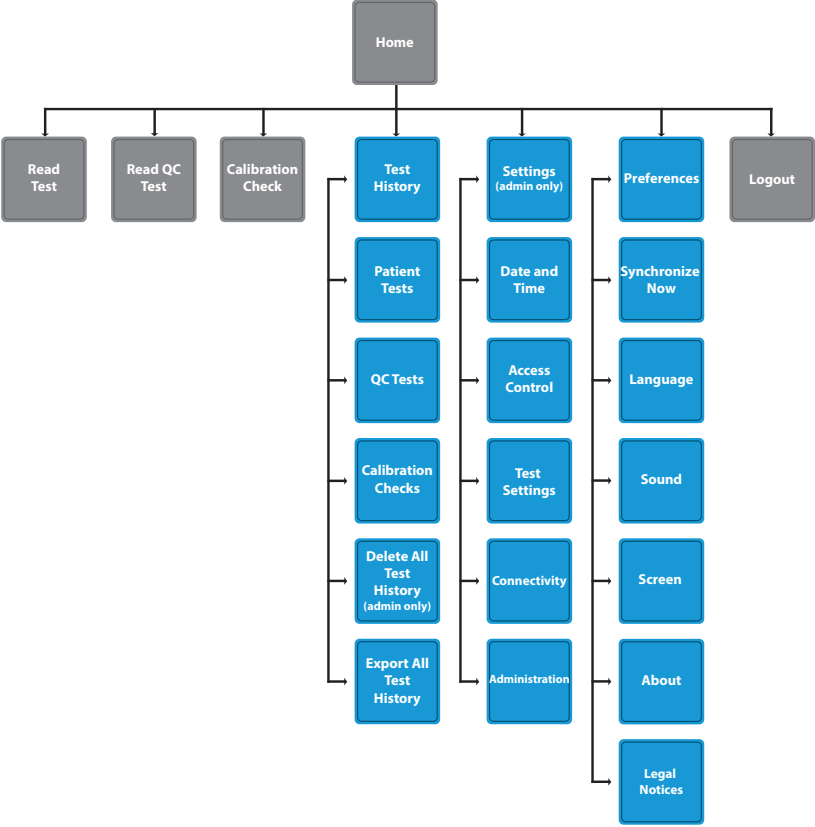
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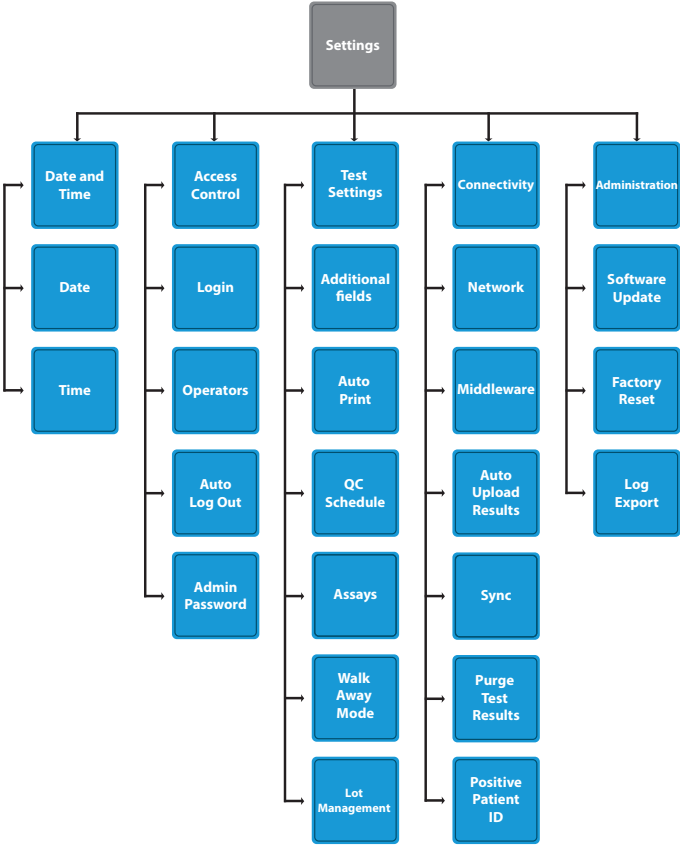
DIGIVAL™ User Manual



Home Screen Menus



Settings Menu (Admin users only)



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1 Introduction

1.1 Intended Use

The DIGIVAL™ is a small bench top instrument to be used in conjunction with Abbott rapid assays.

This document describes the setup, configuration and operation of the DIGIVAL for the qualitative detection of selected Abbott Rapid Tests. Please refer to each specific package insert for details on running the individual tests.

For professional use only. Not for self-testing. For near-patient indications, refer to each specific Abbott Rapid Test package insert.

1.2 Product Description

The DIGIVAL captures, interprets, and transmits results of select Abbott Rapid Tests. It can be used in the laboratory and point of care settings. It is a camera-based instrument that detects the presence and identity of a completed rapid test, analyzes the test and control line, and displays the results (positive, negative or invalid) on a display screen. Results can be printed using an accessory printer connected via USB. In addition, patient test results can be uploaded to a compatible data management system via Ethernet.

When a test is placed in the DIGIVAL, the DIGIVAL identifies the test device type and type of assay by reading the barcodes. It then selects the appropriate test parameters, performs the analysis, and reports results on the screen. Results are stored in memory, and can be printed, if desired, on an optional printer. If connected to a data management system, results are uploaded and are no longer available in memory.

2 Warnings and Safe Use

- ⚠ **Warning:** Failure to comply with the user manual could lead to inaccurate results.
- ⚠ **Caution:** Use only the power supply that is provided with the DIGIVAL. Use the appropriate adaptor on the provided power supply for the region. The correct power supply is required to maintain the safety and electromagnetic compatibility of the DIGIVAL.
- ⚠ **Caution:** Always operate the DIGIVAL on a clean, flat, level and stable surface not in direct sunlight. Do not drop the DIGIVAL.
- ⚠ **Caution:** Never move the DIGIVAL 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. Clean DIGIVAL and surrounding surfaces according to instructions provided in Section 14, “Care & Cleaning.”
- ⚠ **Caution:** Risk of electrical shock. Do not operate the DIGIVAL or the power supply if it has been opened, damaged or exposed to moisture, condensation or rain.
- ⚠ **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:** Do not disassemble or attempt to repair the DIGIVAL or other accessories as there is a risk of damage to the DIGIVAL. The DIGIVAL does not contain serviceable parts and should be returned for repair. Disassembling the DIGIVAL will also void the warranty.
- ⚠ **Caution:** Only operate the DIGIVAL for its intended purpose and in accordance with this user manual and warnings. If the DIGIVAL is used in a manner not specified in the user manual, protection provided by the equipment will be impaired. The DIGIVAL (including power supply) is designed to operate within the manufacturer’s specifications. Do not exceed the manufacturer specifications when in use.
- ⚠ **Caution:** Position the DIGIVAL with clear access to connectors. Keep connected cables clear of work areas such that tripping or catching will not pull the DIGIVAL off its work bench. The mains socket outlet intended for use with DIGIVAL power supply should be located near the DIGIVAL 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:** Do not immerse in water or cleaning solutions.
 - ⚠ **Caution:** Clean only with indicated solutions.
 - ⚠ **Caution:** Patient ID and Test Type cannot be edited once testing has begun.
 - ⚠ **Caution:** Do NOT open the DIGIVAL drawer during testing. The test is not saved until the completed result is displayed.
 - ⚠ **Caution:** Do not reinsert test device once a result has been reported.
 - ⚠ **Caution:** Do not remove the USB memory stick during the software update.
 - ⚠ **Caution:** Care should be taken when handling the tests to avoid potential contamination from debris such as lint, hair and other particulates as these may cause false results.

2.1 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 DIGIVAL, 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 DIGIVAL 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 DIGIVAL in accordance with your organization's security policies and through the user accounts maintained by the DIGIVAL system.
- **Manage and protect your sensitive data:** Results or other data exported from DIGIVAL should be controlled with appropriate laboratory practices.

3 DIGIVAL™ at a Glance

DIGIVAL™, Front View

- ❶ Power On/Off Button
- ❷ Test Insert Tray



DIGIVAL™, Back View

- ❶ Barcode scanner bracket location holes
- ❷ USB port (x1)
- ❸ Power connection
- ❹ Ethernet
- ❺ USB ports (x2)



4 Getting Started - Setup

4.1 Unpacking and inspection

Carefully open packages containing the DIGIVAL and barcode scanner. Inspect the shipping boxes, DIGIVAL and barcode scanner for signs of damage. If any equipment is damaged, notify Abbott immediately.

Check to make sure that the following components are included in the packaging:

- DIGIVAL and power cord/adaptor
- Barcode Scanner Bracket
- DIGIVAL User Manual
- DIGIVAL Quick Start Guide
- Abbott USB Memory Stick

A separate package contains:

- Barcode Scanner
- Barcode Scanner Holster and thumbscrew
- Test insert tray pack (assay specific)
- Calibration Check Card Pack

4.2 Installation and operating conditions

Cautions:

- ⚠ Always operate the DIGIVAL on a clean, flat, level and stable surface not in direct sunlight. Do not drop the DIGIVAL.
- ⚠ Position the DIGIVAL with clear access to connectors. Keep connected cables clear of work areas such that tripping or catching will not pull the DIGIVAL off its work bench. The mains socket outlet intended for use with DIGIVAL power supply should be located near the DIGIVAL and be readily accessible. Abbott recommends that cables are disconnected when not in use for an extended period. Use only the power supply that is provided with the DIGIVAL. Use the appropriate power supply for the region. The correct power supply is required to maintain the safety and electromagnetic compatibility of the DIGIVAL.
- ⚠ 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.

1. Place the DIGIVAL on a clean, flat, level and stable surface within reach of an electrical outlet. Avoid placing the DIGIVAL in direct sunlight. Allow sufficient space to open and close the drawer and to connect the accessories to the connection ports which are located at the back of the DIGIVAL.
2. At first time use, allow the DIGIVAL to adjust to room temperature for at least 30 minutes before using.



3. Connect the barcode scanner holster to the bracket provided with the DIGIVAL, using the thumbscrew.



4. Connect the bracket assembly to the back of the DIGIVAL.
5. Place the barcode scanner in the holster and connect to the USB port at the back of the DIGIVAL.



6. Connect printer to the USB port at the back of the DIGIVAL. (optional)



7. Connect the 12V power cord/ adapter to the DIGIVAL. Plug the appropriate, country-specific adapter into an appropriate electrical outlet.

4.3 Power up and first time login



8. Power Up: With the power connected, press the Power Button on the front of the DIGIVAL to power up and start the DIGIVAL. The power button lights up, and the Scan or Enter Operator ID screen displays.

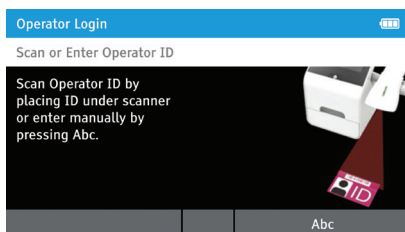


Figure 1: Power up screen

Once the instrument is running, it may be turned off (shut down) by pressing and holding the Power Button for 10 seconds or longer.

Note: The instrument is intended to be used with external power connected. A battery with lightning symbol will appear when power is connected. When disconnected from power, a battery symbol will appear with 3 (or less) bars, depending on remaining charge. When battery level drops to 30%, a Warning message will appear.

To set up your system for the first time, follow the steps below.

- Log in as admin
- Set the date and time
- Set the admin password
- Create operator(s)
- Log out
- Log in as an operator
- Perform a calibration check

1. Log in as "Admin"

The first user to power up the system can log in as "admin." To log in:

Scan or Enter Operator ID: Enter 'Admin' as the login name.

Password: Enter 'admin' for the password.

2. Set the date and time

To set the date and time, tap:

Settings>Set date and time

See Section 7.1, "Date and Time" for more detail.

3. Set the Admin password

To set the Admin password, tap:

Settings>Access Control>Admin password

Enter the new Admin password. See Section 7.2.4, "Set the Admin password" for more detail.

4. Select operator login option

To select options, tap:

Settings>Access Control>Login

Select Operator ID only or Operator ID and Password. See section 7.2.1 for more detail.

5. Create operator(s)

To create operator login permissions, tap:

Settings>Access Control>Operators>Actions>Add

Add at least one operator so that you can perform a Calibration Check. You can return to this screen to add the rest of the staff at any time.

See Section 7.2.2.1, "Add a new Operator."

6. Log out as the admin

To log out, tap:

Home>Log Out

7. Log in as one of the newly created operators.

Scan or Enter Operator ID: Enter the operator login name and tap **OK**.

Password: If a password was specified in the **Create operator** screen, you will be asked to enter your assigned password. Enter it and then tap **OK**.

8. Perform a Calibration Check

When the DIGIVAL is powered on for the first time it will require a calibration check using the provided Calibration Check Card.

To start the check, tap:

Home>Calibration Check

Screen instructions guide you through the Calibration Check procedure. See Section 6, "DIGIVAL Calibration" for more detail.

5 DIGIVAL™ Touchscreen

Information can be entered into the DIGIVAL by tapping the appropriate touchscreen keys, or by using the barcode scanner.

5.1 Home Screen

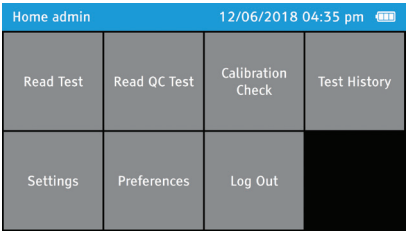


Figure 2: Home Screen

Home Screen: Displays buttons for access to:

- Read a Test – See Section 9, “Reading a Test”
- Read QC Test– See Section 10, “Reading a QC Test”
- Calibration Check– See Section 6, “DIGIVAL Calibration.”
- Test History– See Section 12, “Test History.”
- Settings (Admin only) – See Section 7, “Settings Menu.”
- Preferences– See Section 8, “Preferences Menu.”
- Log Out

The time, date and battery status are displayed in the top right hand corner of the screen. The currently logged in Operator is displayed at the upper left of the screen.

5.2 Navigation

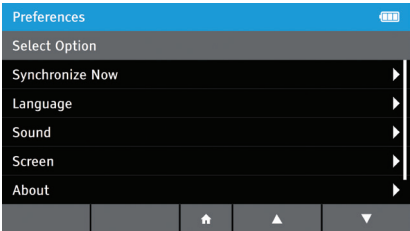


Figure 3: Preferences menu with navigation bars

Tap navigation arrows to scroll through menus and advance to submenus.
Home: Tap the **Home** icon at any time to return to the Home Screen.

5.3 Barcode Scanner/Onscreen Keyboard

Two onscreen keyboards (QWERTY and Numeric) are used to enter specific information into the DIGIVAL. Use the **?123** or **Abc** keys to switch between the alphanumeric and numeric keypads. Information can be entered by tapping the keypad keys or by scanning with the barcode scanner.

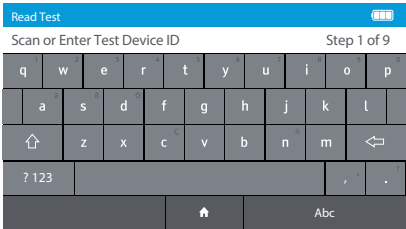


Figure 4: QWERTY Keyboard

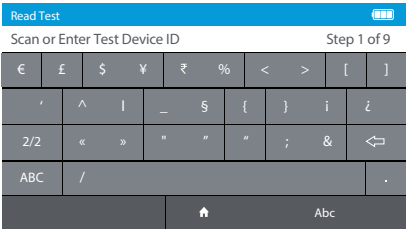


Figure 5: Numeric Keypad 1/2

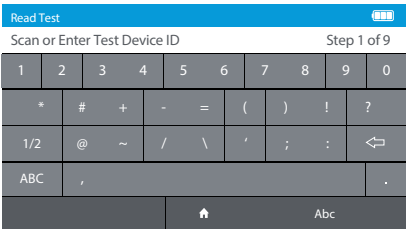


Figure 6: Numeric Keypad 2/2

6 DIGIVAL™ Calibration

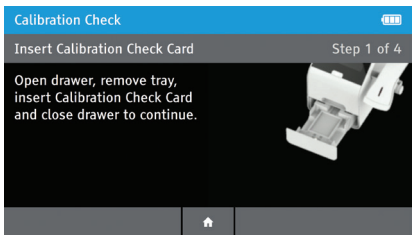
Home>Calibration Check

A calibration check verifies that the DIGIVAL's internal camera is functioning correctly, with a lens free from debris, and that the DIGIVAL is working to specification.

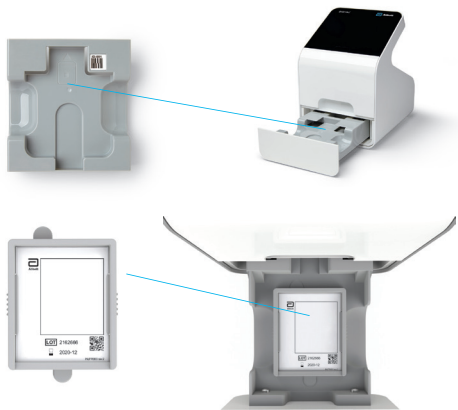
To ensure proper function, a calibration check of the DIGIVAL must be performed regularly; at least every 30 days. If a calibration check has not been done in the last 30 days, an error message displays. No tests can be processed until the calibration check is up to date.

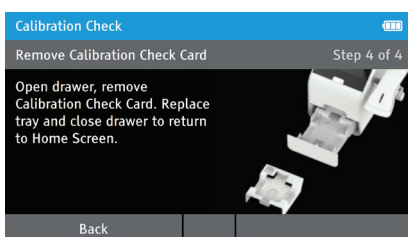
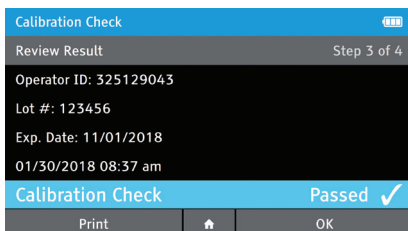
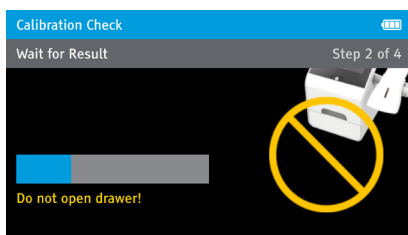
Two Calibration Check Cards, supplied with an expiry date, are provided for this purpose. Additional Calibration Check Cards can be ordered. See Section 20, "Ordering and Contact Information."

To perform calibration:



1. From the **Home** menu, tap **Calibration Check**. The system verifies that there is enough memory to start the calibration check and then guides you through the calibration check steps:
2. Open the drawer and remove the tray.
3. Place the Calibration Check Card into its position as shown on the screen.

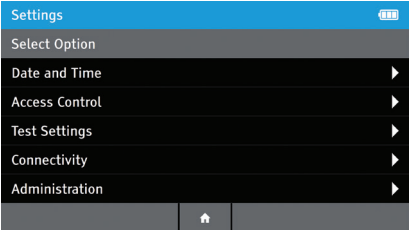




4. Close the drawer. The DIGIVAL automatically starts the calibration check. Do not open the drawer.
5. When the calibration check is complete, the result is displayed for review.
 - If Calibration Check passes, tap **OK** to proceed to the next step.
 - If it fails, the card can be cleaned using a soft, lint-free cloth to remove dust or debris. Handle the calibration check card with gloves to prevent against fingerprints that may effect the reading. Also see Section 16, E.18.
 - If a printer is connected, you can tap **Print** to print a report. The printing screen displays.
6. When printing has finished, open the drawer, **remove the Calibration Check Card and carefully return it to the zip lock bag to protect it from sunlight**, and replace the tray.
7. The calibration check is complete.

7 Settings Menu (Admin Access Only)

Home>Settings (Admin Access Only)



The Settings menu is used to configure the DIGIVAL. It is only available when the Admin is logged on.

Settings are saved even when the power is off.

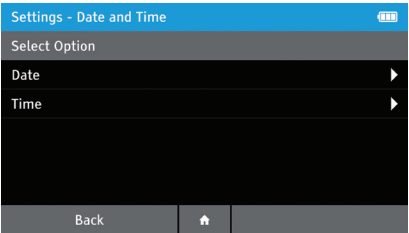
Settings include:

- Date and Time
- Access Control
- Test Settings
- Connectivity
- Administration

Use the arrows on the right side of the screen to scroll through menus.

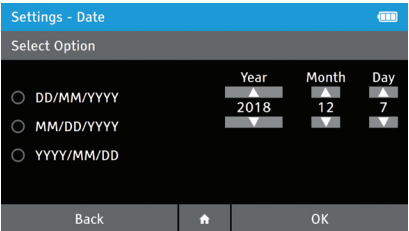
7.1 Date and Time (Admin Access Only)

To update the date and time, tap: **Settings>Date and Time**



Select Date or Time.

The Date screen displays:

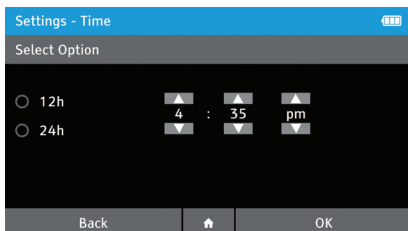


Tap to select the preferred date format.

Set the correct date using the up and down arrow keys on the touch screen to move between **Year**, **Month** and **Day**.

Tap **OK** to continue.

The Time screen displays:



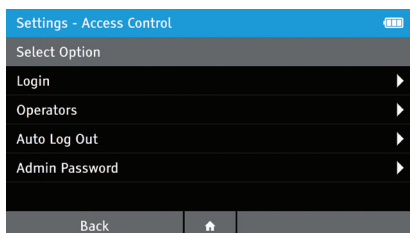
Tap to select either a 12 hour or 24 hour display.

Set the correct time using the up and down arrow keys.

Tap **OK** to advance.

7.2 Access Control

Home>Settings>Access Control

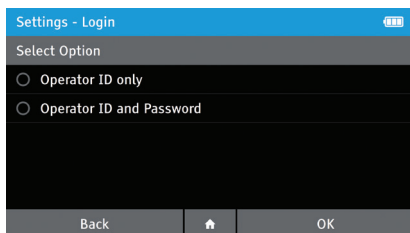


Use the Access Control menu to determine who can access the system and which functions they can perform.

7.2.1 Login (Admin Access Only)

Home>Settings>Access Control>Login

Login allows the Admin to configure whether Operator ID passwords are required in order to allow access to the DIGIVAL. The selected option will apply to all Operators with the exception of the Admin, who will always be required to use a password when logging on as 'Admin'.



Operator ID only:

If Operators do not require passwords, tap **Operator ID only** and tap **OK**.

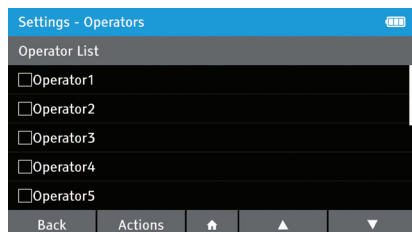
If the system is changed from **Operator ID & Password** to **Operator ID Only**, existing passwords are retained in the event the Admin selects Operator ID & Password in the future.

Operator ID and Password:

If a password is required, tap **Operator ID and Password** and tap **OK**.

If the system is changed from **Operator ID Only** to **Operator ID & Password**, Operator passwords will need to be assigned individually by the Admin before Operators can login. The Admin can change each Operator's password individually, as needed. See Section 7.2.2, "Operators."

7.2.2 Operators (Admin Access Only)



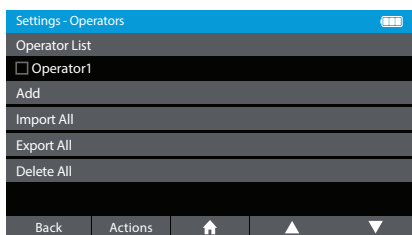
To set up Operators, tap:

Home>Settings>Access Control>Operators

When the Operators menu is opened, the list of operators for the DIGIVAL is displayed:

7.2.2.1 Add a New Operator

To add a New Operator, from **Home>Settings>Access Control>Operators**:



1. Tap **Actions**.
2. Tap **Add**. The keypad displays, with the message, "Scan Operator ID or enter manually."
3. Enter the Operator ID (for example the Operator's name) or scan Operator's ID using the electronic barcode, then tap **OK**.

The Operator ID must be 2-20 characters, and cannot contain spaces or special characters. Operator ID's are not case sensitive. Use the **?123** or **Abc** keys to switch between the alphanumeric and numeric keypads.

A unique Operator ID is required for each Operator. If a duplicate Operator ID is entered, the DIGIVAL prompts you to use a different ID.

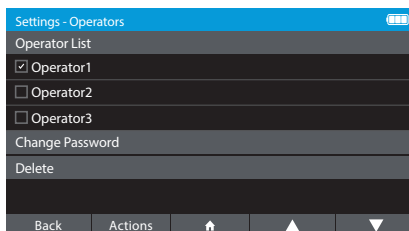
4. If you have set **Operator ID & Password** to require passwords in the Login menu, the DIGIVAL prompts the Operator for a password. See 7.2.2, “Operators.” Only the Admin can change an Operator's password. Passwords are case-sensitive and must have 4-20 characters.

Note: Use the ?123 or Abc keys to switch between the alphanumeric and numeric keypads.

5. Enter the password. The message, “Confirm New Operator Password” displays.
6. Reenter the password and tap **OK**.

7.2.2.2 To delete Operators, or to change their password

From **Home>Settings>Access Control>Operators:**



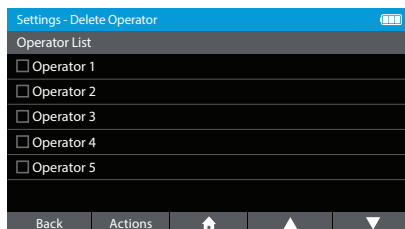
1. Select the Operator by tapping the checkbox next to the operator's name.
 - Use the arrows at the bottom of the screen or swipe to move up or down the list.
 - To de-select an operator, tap the checkbox a second time.
2. Tap **Actions**.

Changing an Operator's password:

Passwords are case-sensitive and must have 4-20 characters. Use the ?123 or **Abc** keys to switch between the alphanumeric and numeric keypads.

1. After selecting the operator in **Home>Settings>Access Control>Operators**, tap **Actions**.
2. Tap **Change Password**.
3. Enter the new password and tap **OK**. The screen asks you to confirm the new password:
4. Enter the password again and tap **OK**.
5. Tap **OK** to finish.

Deleting an Operator:

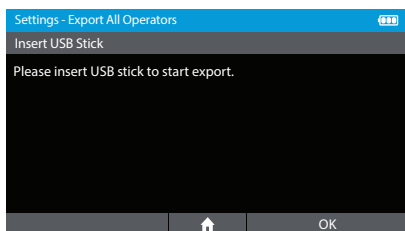


You can delete one or all operators, but you cannot delete Admin. Deleting an Operator is permanent. Once deleted, the Operator profile will be lost. Test results already stored in the DIGIVAL performed by this Operator will not be affected.

To delete a current operator:

1. From **Home>Settings>Access Control>Operators**, select the Operator by tapping the checkbox next to the operator's name.
 - Use the arrows at the bottom of the screen or swipe to move up or down the list.
 - To de-select an operator, tap the checkbox a second time.
2. Tap **Actions**.
3. Tap **Delete**.
4. Tap **OK** to permanently delete the Operator.
5. Tap **OK** to finish.

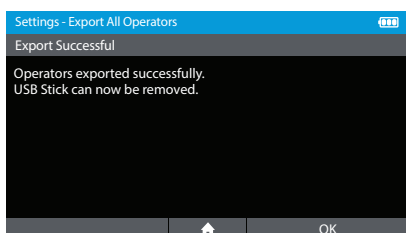
Exporting an Operator List:



1. From **Home>Settings>Access Control>Operators**, tap **Actions**.
2. Tap **Export All**.

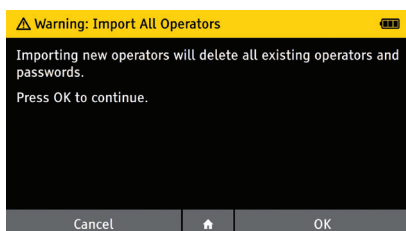


3. Insert USB memory stick to start export.

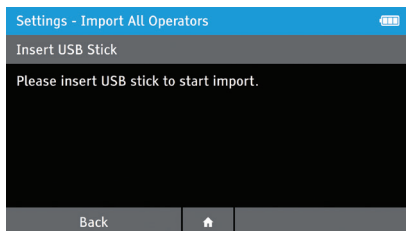


4. Screen will indicate successful Export and will prompt removal of USB memory stick.

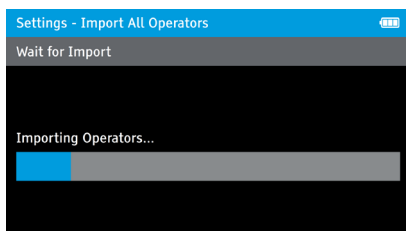
Importing an Operator List:



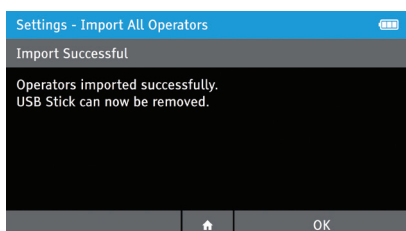
1. From **Home>Settings>Access Control>Operators, tap Actions.**
2. Tap **Import All.**
3. A Warning will display: "Importing an Operator List will delete all existing operators and passwords, and will replace it with the new list. Tap **OK** to continue, or Cancel to return to the menu."



4. Insert the USB memory stick that contains the exported Operator List.

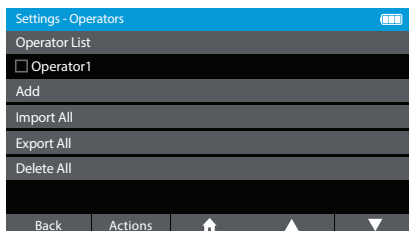


5. The instrument will detect the drive and will import the new operator list.



6. When the instrument indicates the Import is Successful, the USB Memory Stick can be removed.

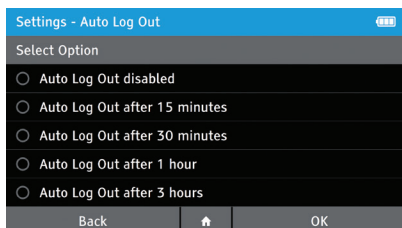
Deleting all Operators:



1. From **Home>Settings>Access Control>Operators**, tap **Actions**.
 2. Tap **Delete All**.
 3. Tap **OK** to delete all operators.
- All operators are deleted. Tap **OK** or **Home** to exit.

7.2.3 Auto Log Out (Admin Access Only)

Home>Settings>Access Control>Auto Log Out



The Auto Log Out Menu allows the Admin to select whether or not the DIGIVAL logs an operator out after a period of inactivity.

- If you do not want Operators to be automatically logged out after a specified time, select **Auto Log Out disabled** and then tap **OK**. Another Operator will not be able to log in until the current Operator logs out.
- If you want Operators to be automatically logged out after a selected period of inactivity, select desired **Auto Log Out time period** and tap **OK**.

7.2.4 Set the Admin Password

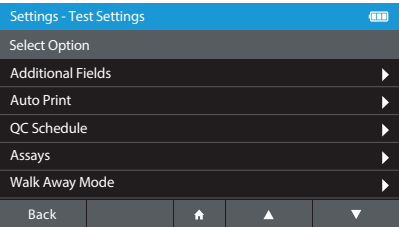
To set a new Admin password:

1. Tap **Home>Settings>Access Control>Admin Password**.
2. Use the keypad to enter the new Admin password.
Passwords are case-sensitive and must have 4-20 characters. Use the **?123** or **Abc** keys to switch between the alphanumeric and numeric keypads.
3. Tap **OK**.
4. Re-enter the password and tap **OK**.

Note: If you forget the Admin password, you will need to contact Abbott Technical Support for assistance.

7.3 Test Settings

Home>Settings>Test Settings

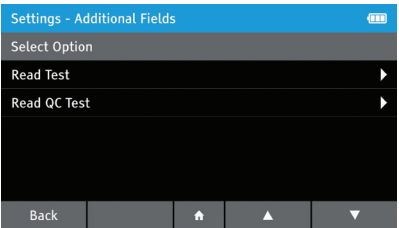


Use the Test Settings menu to select the desired Test option.

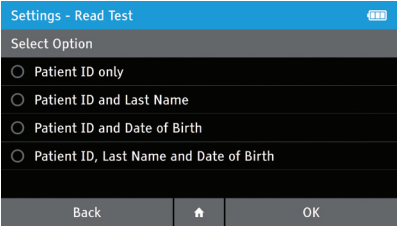
For additional Test Setting options, including Lot Management, tap the down arrow on the bottom right of screen.

7.3.1 Additional fields

Home>Settings>Test Settings>Additional Fields>Read Test



Use the Additional Fields menu option to configure additional data fields to be collected when running a test: Choose Read Test for patient test options, or Read QC Test for QC test options.



Choose one of the Read Test options to configure additional fields to be collected when running a patient test. **(Note: Default is Patient ID only.)** Tap **OK** to save the new setting.

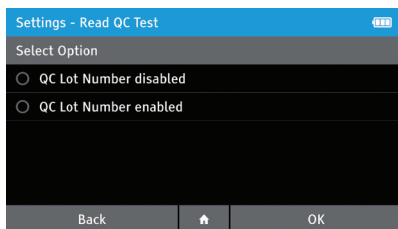
Patient ID only - The DIGIVAL will only prompt the user for a Patient ID

Patient ID and Last Name - The DIGIVAL will only prompt the user for a Patient ID and Last Name

Patient ID and Date of Birth - The DIGIVAL will only prompt the user for a Patient ID and Date of Birth

Patient ID Last Name and Date of Birth - The DIGIVAL will prompt the user for a Patient ID, Last Name and Date of Birth

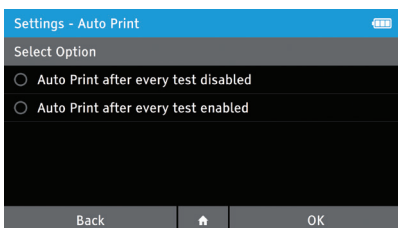
Home>Settings>Test Settings>Additional Fields>Read QC Test:



Entry of QC lot numbers may be enabled or disabled. If enabled, the DIGIVAL will prompt the user for the QC lot number when running a QC test. Tap **OK** to save the new setting.

7.3.2 Auto Print

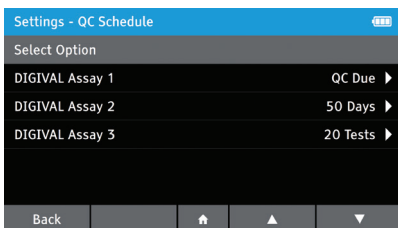
Home>Settings>Test Settings>Auto Print



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

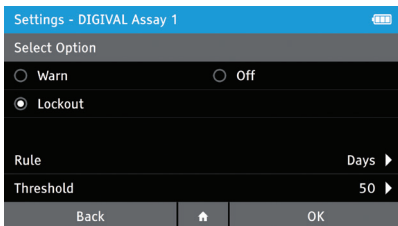
7.3.3 QC Schedule

Home>Settings>Test Settings>QC Schedule



The **QC Schedule** Menu allows the Admin to configure QC schedules for each assay. Each assay has its own independent QC schedule settings. Touch the row for any assay to configure its QC schedule settings.

The **QC Schedule** assay menu allows the Admin to configure a QC schedule for a single assay. QC schedules apply to the assay overall, rather than to individual test device lots (as with **Lot QC**).



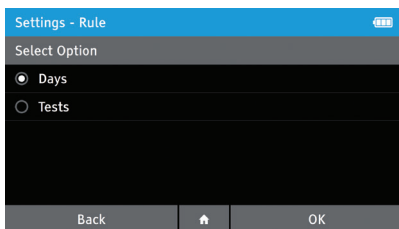
Select **Warn** or **Lockout** to enable a QC schedule for this assay. When **Warn** or **Lockout** is selected, the **Rule** and **Threshold** options are displayed. Touch the **Rule** or **Threshold** option to configure the settings.

Select **Off** to disable the QC schedule for this assay (default).

In **Warn** and **Lockout** modes, the DIGIVAL checks the assay **Threshold** each time a patient test is run. If the threshold has been reached:

- In **Warn** mode, the DIGIVAL displays a warning that QC tests should be run. The user may acknowledge the warning and proceed with the patient test.
- In **Lockout** mode, the DIGIVAL displays an error message indicating that QC tests must be performed. The DIGIVAL prevents the user from running a patient test until the required QC tests have been run.

In all cases, successful QC consists of a positive QC test and a negative QC test, both with a result of **Pass**.



Select **Days** to configure a QC schedule that is based on the number of days since the last successful QC. Select **Tests** for a schedule based on the number of patient tests since the last successful QC.

Tap **OK** to save the new setting.

Enter a threshold value between 1 and 999.

When the **Rule** is set to **Days**, this value represents the number of days that may elapse after successful QC before QC will be required again.

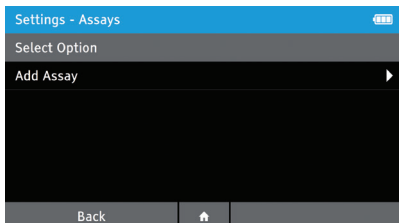
When the **Rule** is set to **Tests**, this value represents the number of patient tests that may be run after successful QC before QC will be required again.

Tap **OK** to save the new setting.

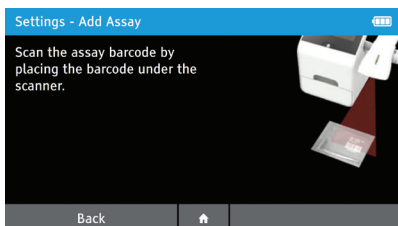
7.3.4 Assays

Home>Settings>Test Settings>Assays

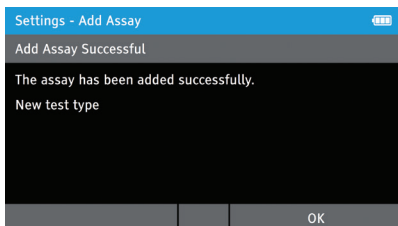
Use the Assays menu option to configure new assays on the DIGIVAL, as they become available.



1. Tap **Add Assay**



2. Scan the 2D barcode provided with the new assay kit.

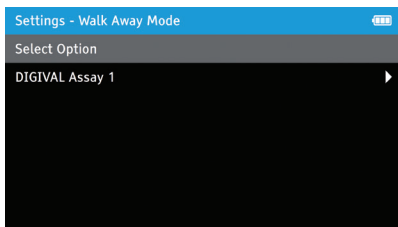


3. The instrument will reboot itself to complete the new assay configuration.

Note: "Assay is already up-to-date" will display on screen if attempt is made to add an existing assay.

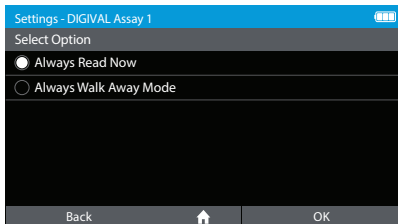
7.3.5 Walk Away Mode

Home>Settings>Test Setting>Walk Away Mode



Use the **Walk Away Mode** menu option to configure patient tests to be run in **Walk Away Mode**. Walk Away Mode allows the DIGIVAL to time the test for the user, so that the read occurs at the time specified in that assay's product insert.

Note: Not all assays will have this option. Refer to Product Insert for details.



1. Tap **Walk Away Mode** from the Test Settings menu.
2. Tap the assay to configure.
3. Select the read type:

Always Read Now: All tests on the DIGIVAL will read a test immediately after inserting a test device.

Always Walk Away Mode: The DIGIVAL will always time assay development and interpret the test result at the read time.

7.3.6 Lot Management

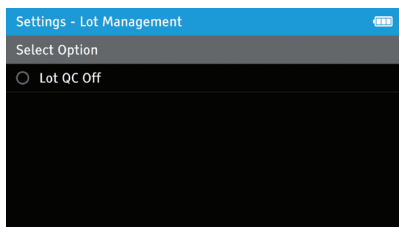
Home>Settings>Test Settings>Lot Management

The **Lot Management** menu allows the administrator to specify how Lot QC is handled. Lot QC refers to the requirement of performing successful QC on any new lot of test devices prior to running patient tests with the lot.

When **Lot QC is on**, the DIGIVAL checks for prior successful QC when a patient test is run. If successful QC has not been performed on the test device lot, the DIGIVAL displays an error message indicating that QC tests must be performed.

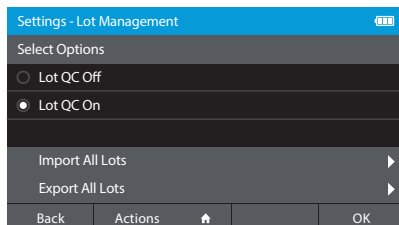
The DIGIVAL prevents the user from running a patient test with that lot until the required QC tests have been run.

When **Lot QC is off**, the DIGIVAL allows patient tests to be run without checking for prior QC on the test device lot.

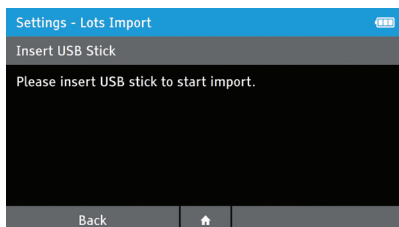


Select the desired Lot QC setting using the touchscreen. Tap **OK** to save the new setting and return to Test Settings menu.

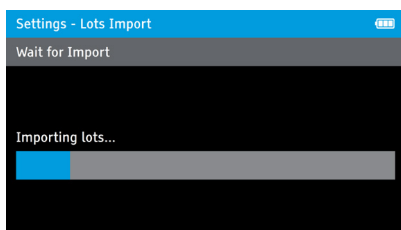
The import/export features may be used to transfer information about successful QC from one instrument to another.



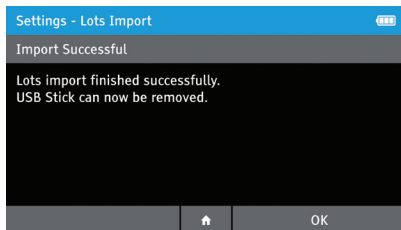
Tap **Actions** for the **Import All Lots** and **Export All Lots** options. Use **Export All Lots** on the DIGIVAL on which successful QC has been performed, then **Import All Lots** on other DIGIVAL(s).



To **Import** or **Export All Lots**, tap the corresponding menu option. The DIGIVAL displays a prompt to insert a USB memory stick. The DIGIVAL automatically starts the import or export when a memory stick is inserted.



The DIGIVAL displays a progress bar while importing or exporting the list of lots.

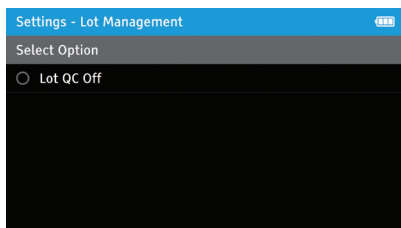


When the import or export is complete, the result is displayed and the memory stick may be removed.

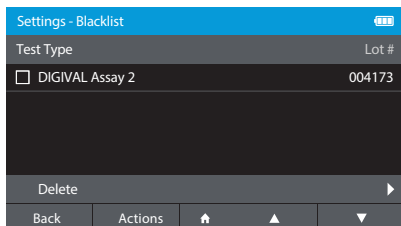
7.3.7 Blacklist

Home>Settings>Test Settings>Lot Management>Blacklist

The lot blacklist feature provides an administrator the ability to block the usage of specific lots of test devices. This feature overrides all other settings on the instrument and is intended to prevent testing with a problematic lot or lots.



Tap **Blacklist** in lower left screen.

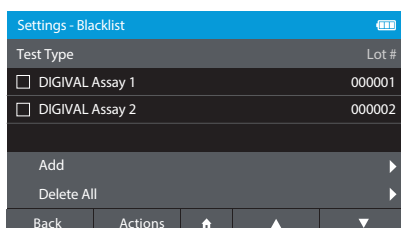


The list of blacklisted lots is displayed, including the test type for each lot, if applicable.

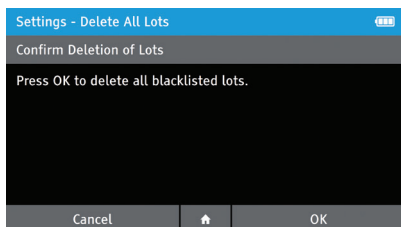
To remove a specific lot from the blacklist, check the box for the lot using touchscreen, then tap **Actions**, then **Delete**.

Tap **OK** to confirm and remove the lot from the Blacklist.

Tap **OK** to continue.



To remove all lots from the blacklist, tap **Actions** and **Delete All** using touchscreen.



Tap **OK** to confirm and remove the lot from the blacklist.

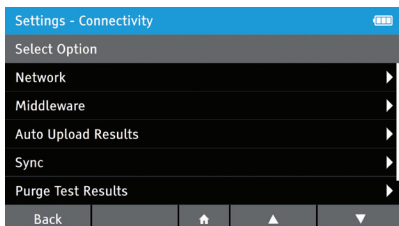
Tap **OK** to continue.

To add a lot to the blacklist, tap **Actions** then **Add** using touchscreen. Scan the barcode or enter manually using the touchscreen keypad.

Tap **OK** to continue.

7.4 Connectivity

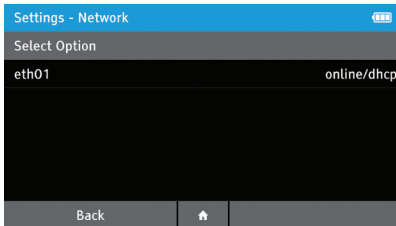
Home>Settings>Connectivity



Use the Connectivity menu to configure the DIGIVAL network interface and the connection to a middleware system. With the appropriate middleware system, these features allow patient test results to be transmitted electronically to a patient's electronic medical record, eliminating the need to enter the results by hand.

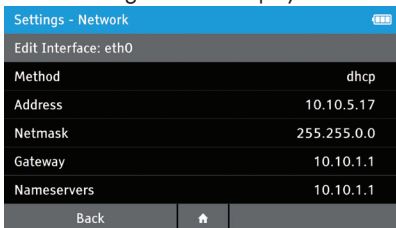
7.4.1 Network Interface Settings

Home>Settings>Connectivity>Network



Use the Network menu to configure the Ethernet interface on the DIGIVAL. To view or edit the interface settings, tap the interface name ("eth0").

The following screen is displayed:

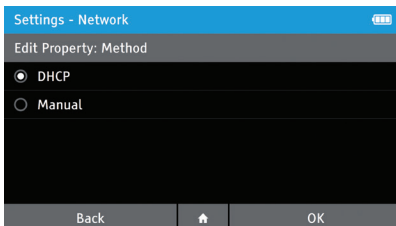


To configure the Ethernet interface, first select the appropriate Method (DHCP or Manual). The DHCP method causes the DIGIVAL to obtain its network configuration from a DHCP server on the network. This is the simpler of the two methods and is the recommended option if a DHCP server is available. When the DHCP method is used, the remaining interface settings do not need to be configured.

If no DHCP server is available, the interface must be configured using the Manual method. In this case, the other interface settings must be set individually and should be configured according to information provided by your network administrator.

7.4.1.1 Network Interface Settings - Method

To change the Method setting, tap the Method line on the screen and the Edit Property: Method screen is displayed:



Tap the desired Method, then tap **OK** to save the new setting.

7.4.1.2 Network Interface Settings - Other Properties

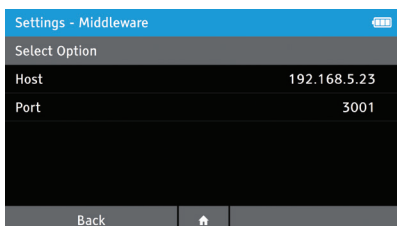
To change the other interface properties (Address, Netmask, Gateway, and Nameservers), tap the corresponding line on the screen and the Edit Property screen is displayed. The DIGIVAL must be connected for other screens to show.

Use the keypad to enter the desired value for the selected property. Values should be in the format 0.0.0.0, where each '0' represents a number in the range 0-255. Tap **OK** to save the new value and return to the main Network Settings screen.

7.4.2 Middleware Settings

Home>Settings>Connectivity>Middleware

Use the Middleware menu to configure the DIGIVAL to connect to a middleware system designed for use with the DIGIVAL. Your network administrator or middleware vendor should provide you with the necessary configuration values.

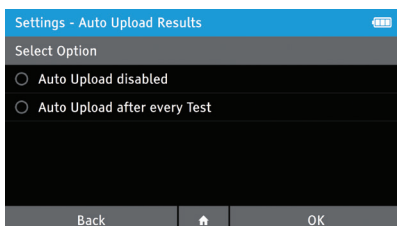


To edit the Host setting, tap the Host line and the Edit Property screen appears. Use the keypad to enter either the name or the IP address of the middleware server. If using an IP address, the value should be in the form 0.0.0.0, where each "0" represents a number in the range 0-255. Tap **OK** to save the new value and return to the Middleware Settings menu.

To edit the Port setting, tap the Port line and the Edit Property screen appears. Use the keypad to enter the port number to connect to on the middleware server. The port number should be a numeric value in the range 1-65535. Tap **OK** to save the new value and return to the Middleware Settings menu.

7.4.3 Auto Upload Results

Home>Settings>Connectivity>Auto Upload Results



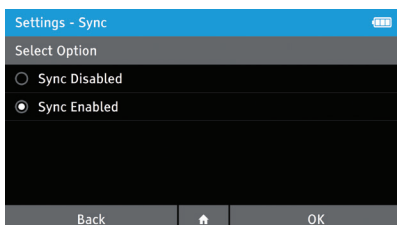
Use the Auto Upload Results menu to select whether patient test results should be uploaded to the middleware system at the conclusion of each test. If this option is disabled, patient test results can be uploaded manually to the middleware system from the Preferences menu.

Uploading results to a middleware system requires that the network interface and middleware settings be configured properly as described in sections 7.4.1 and 7.4.2.

To change the Auto Upload Results setting, tap the desired option then tap **OK** to save the new setting and return to the Connectivity Settings menu.

7.4.4 Sync Settings

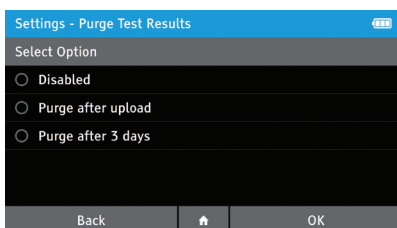
Home>Settings>Connectivity>Sync



Use the Sync menu option to enable or disable periodic connections to a connected middleware system. If Sync is enabled, the DIGIVAL connects to the middleware system every 10 minutes to ensure it has the latest configuration settings, operator list, allowed lots list, and other settings as configured in the middleware system.

7.4.5 Purge Test Results

Home>Settings>Connectivity>Purge Test Results



Use the Purge Test Results menu option to configure the frequency that the DIGIVAL purges test results after uploading them to the configured middleware.

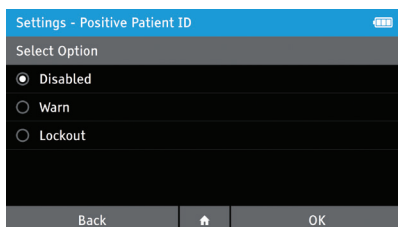
Disabled (Default): The DIGIVAL will not purge any previously uploaded test results.

Purge after upload: The DIGIVAL will purge test results on the DIGIVAL immediately after they've been uploaded to the configured middleware.

Purge after 3 days: The DIGIVAL will purge test results on the DIGIVAL three days after they were successfully uploaded to the configured middleware.

7.4.6 Positive Patient ID

Home>Settings>Connectivity>Positive Patient ID



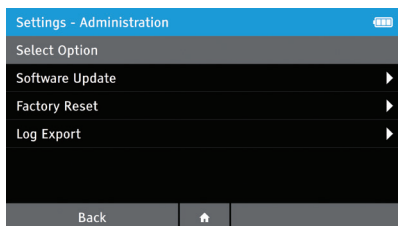
Use the Positive Patient ID menu option to enable a confirmation step in the Read Test workflow to verify the identity of the patient. Note that this feature requires a middleware system that supports patient queries.

If this option is set to **Warn** or **Lockout**, the Read Test workflow is enhanced as follows: after the patient ID is entered or scanned, the DIGIVAL sends a request to the middleware system for the name and date of birth of the patient. The name and date of birth are then displayed on the DIGIVAL so that the user can verbally confirm this information with the patient.

If this option is set to **Warn**, the DIGIVAL allows the user to manually enter the name and date of birth if the data cannot be successfully confirmed against the middleware system. If the option is set to **Lockout**, the user cannot continue with the test if the data is not successfully verified.

7.5 Administration

Use the Administration menu for software updates, factory reset, and log export.



For Software Update information, refer to Section 13.

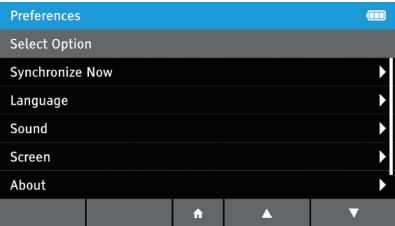
Factory Reset will delete all test results and settings will be reset to factory default. See W.7 for further information.

Log Export is used for exporting operations performed on the instrument to a USB memory stick.

8 Preferences Menu

Home>Preferences

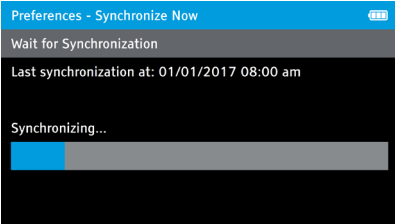
The **Preferences** menu includes:



- **Synchronize Now:** Allows user to force an immediate synchronization with the middleware system.
- **Language:** Change screen text to other language.
- **Sound:** Turn sound on or off.
- **Screen:** Adjust brightness of screen and enable screen saver.
- **About:** View information about the DIGIVAL.
- **Legal Notices:** View license information about open-source software used in the DIGIVAL.

8.1 Synchronize Now

Home>Preferences>Synchronize Now



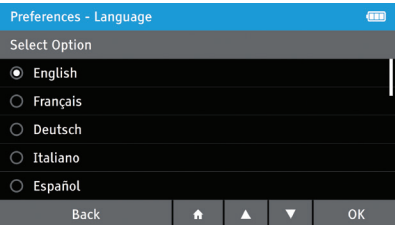
Tap **Synchronize Now** to sync data with configured middleware system. This ensures that all test results are uploaded and that the DIGIVAL has the latest settings such as operator list and allowed lots list.

Tap **OK** to return to Preferences Menu.

8.2 Language

Home>Preferences>Language

To change the language of the screen text:



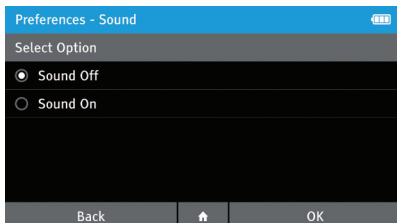
Tap the button next to the desired language. Swipe to scroll for additional languages.

Tap **OK** to save your change. The DIGIVAL prompts you to reboot. When the DIGIVAL is powered on again, screens are displayed in the selected language.

8.3 Sound

Home>Preferences>Sound

To turn sound on or off:

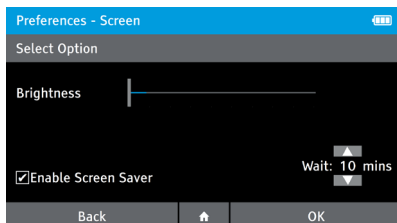


Tap the button next to Sound Off or Sound On.

Tap **OK** to save the settings and return to the Preferences Menu.

8.4 Screen

Home>Preferences>Screen



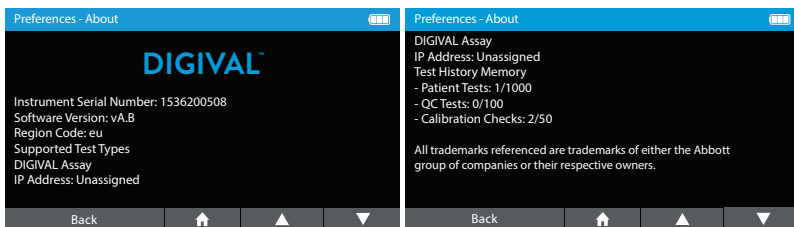
Reduce brightness of screen by scrolling left on touchscreen.

Tap the button next to screen saver to enable screen saver. Use up and down arrows to choose wait time.

If enabled, Screen Saver will turn display off and power button will blink when pre-set time is reached. To deactivate the Screen Saver, touch the screen or press power button.

8.5 About (DIGIVAL™ Information)

Home>Preferences>About



The **About** screen displays information about the DIGIVAL including:

- **DIGIVAL Serial Number**
- **Software version**
- **Supported test types**
- **IP address**
- **Test history memory**

Tap **Back** to return to the Preferences menu.

8.6 Legal Notices

Home>Preferences>Legal Notices

Use the Legal Notices menu option to view license information for any open-source packages used within the DIGIVAL software.

9 Reading a Test

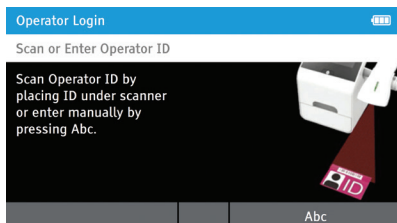
Caution:

⚠ **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. Clean the DIGIVAL and surrounding surfaces according to instructions provided in Section 14, "Care and Cleaning."**

Caution:

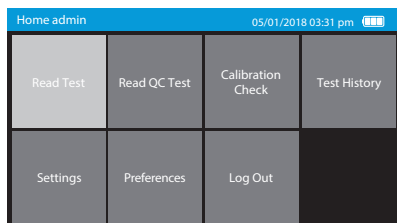
⚠ **Abbott assays may have varying CLIA complexity levels. Please ensure the CLIA complexity of the assay you are using is appropriate for your Laboratory.**

When the DIGIVAL is powered on, or after another operator has logged out, the **Scan or Enter Operator ID** screen displays.



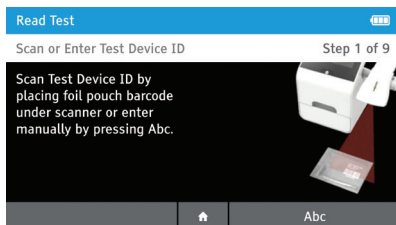
1. Enter your Operator ID using the barcode scanner, or tap **Abc** to access the keypad and enter it manually.
2. If a password is required (as specified by the Admin during setup), the **Enter Password** screen displays. Enter your password and tap **OK**. The **Home** screen displays.

Note: Use the ?123 or Abc touchkeys to switch between the alphanumeric and numeric keypads.



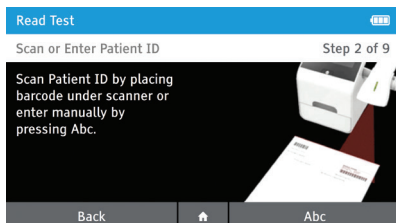
3. Tap **Read Test**. The **Scan or Enter Test Device ID** screen will be displayed.

Note: The step numbers will vary depending on the workflow options chosen.

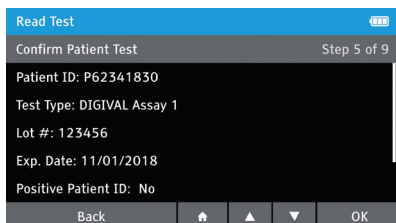


4. Scan or enter the Test Device ID.

- To scan: Place the barcode on the foil pouch under the barcode scanner.
- To enter it manually: Tap **Abc** to access the keypad and then **?123** to access the numeric keypad. Enter the number printed on the foil pouch (below the barcode) and then tap **OK**.



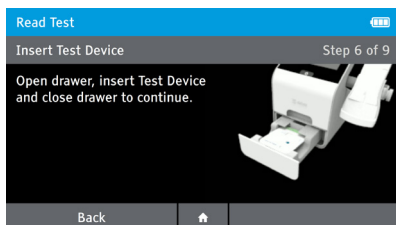
5. Scan Patient ID by placing the Patient ID barcode under the barcode scanner, or tap **Abc** to enter it manually using the keypad. The Patient ID must be 2-20 characters, may contain alphanumeric and special characters such as # and *, and have no spaces. Patient IDs are case-sensitive. User is prompted to enter additional patient fields if configured.



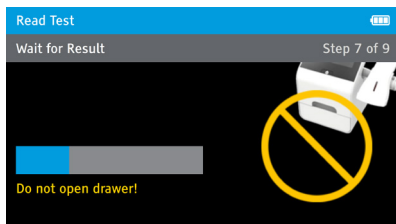
6. Confirm Patient and Test information. Check that the Patient and Test information is correct and tap **OK** to confirm. If the Patient information is not correct, tap **Back** to return to the previous screen to reenter.

Caution:

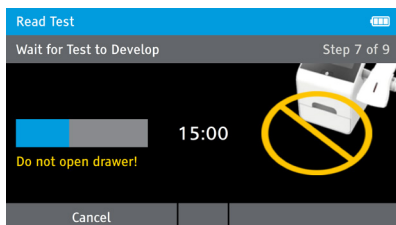
⚠ **Patient information and Test Type cannot be edited once testing has begun.**



7. Refer to assay Product Insert for sample preparation and assay procedure. Insert Test Device at appropriate time according to **Read Mode** chosen.



- **Read Now Mode:** At the read time indicated in assay instructions, open drawer, insert test device, and close drawer to continue. Do NOT open drawer again until result is displayed.



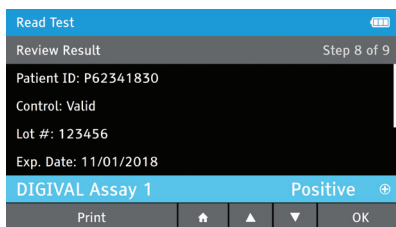
- **Walk Away Mode:** Once the test device is securely closed, immediately open the drawer, insert test device and close the drawer to continue. The DIGIVAL will time the test development and read the result at the read time. Do NOT open the drawer again until the result is displayed.

Do not read Test Results before or after their indicated read time, as the results may not be correct.

If the DIGIVAL is configured to automatically upload test results, the result will be uploaded to the configured middleware system at this point.

Caution:

- ⚠ **Do NOT open the DIGIVAL drawer during testing. The test is not saved until the completed result is displayed.**
- ⚠ **Never move the DIGIVAL while a test is in progress.**

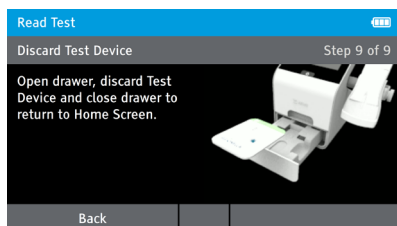


8. When a test completes successfully, results are displayed on the screen, with Positive or Negative result. If a test error occurs, 'Invalid' displays. Refer to specific package insert for further details on test result.

If the optional printer is set up, tap **Print** to print the test result. Tap **Home** to return to the home screen or tap **OK** to continue.

If the DIGIVAL is set to Auto Print, the test result will automatically print.

Note: *If the assay contains more than one test line, the individual results of each test line will be reported.*



9. Open the drawer and discard the used Test Device. The Test Device can now be removed from the DIGIVAL and disposed of according to federal, state and local regulations.

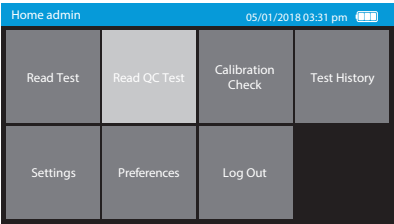
⚠ Do not reinsert test device once a result has been reported.

Close the drawer. The display returns to the **Home** screen.

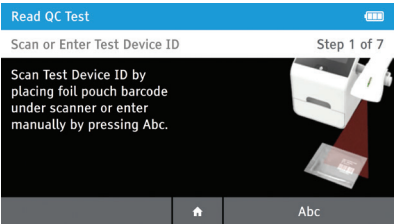
10 Reading a QC Test

Home>Read QC Test

Abbott test kits contain positive and negative external controls. Refer to the product insert for the test that you are using for further information regarding the QC test requirements. Further controls may be tested in order to conform to local, state and/or federal regulations, accrediting groups, or the lab's standard Quality Control procedures.

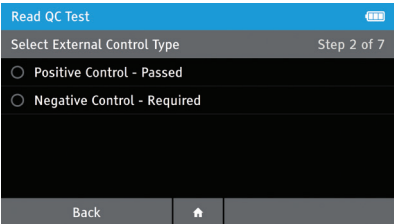


To read a QC Test, tap **Home>Read QC Test**. This starts the DIGIVAL's Self Check. The **Scan or Enter Test Device ID** screen will be displayed.



STEP 1: Scan or enter the Test Device ID.

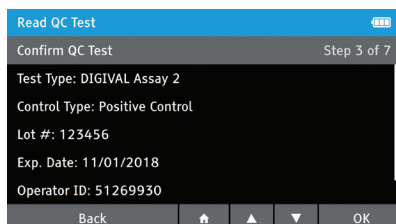
- **To scan:** Place the barcode on the foil pouch under the barcode scanner.
- **To enter it manually:** Tap **Abc** to access the keypad and then **?123** to access the numeric keypad. Enter the number printed on the foil pouch (below the barcode) and then tap **OK**.



STEP 2: Select the QC test to be run by tapping the button next to the desired test.

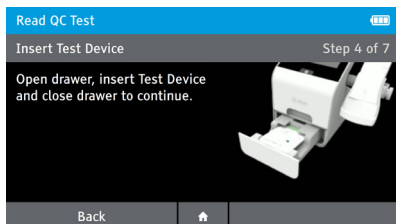
Tap **OK** to continue.

The **Confirm QC Test** screen displays.



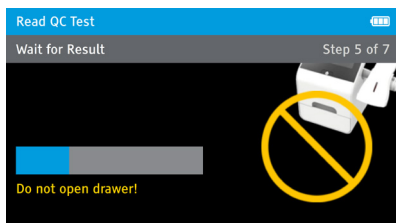
STEP 3: Verify that the test type matches the QC sample intended for testing and tap **OK** to confirm.

If the incorrect QC test has been selected tap **Back** to return to the previous screen.



STEP 4: Refer to specific test Product Insert for QC preparation and test procedure. Insert Test Device at appropriate time according to **Read Mode** chosen.

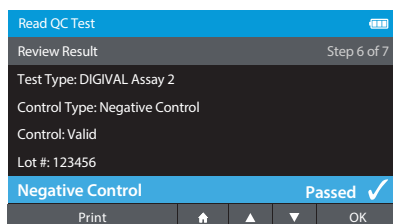
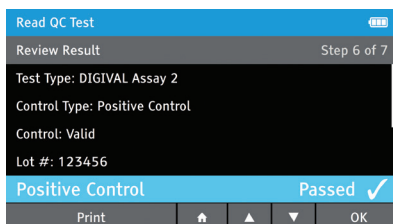
- **Read Now Mode:** At the read time indicated in assay instructions, open drawer, insert test device, and close drawer to continue. Do NOT open drawer again until result is displayed.
- **Walk Away Mode:** Once the test device is securely closed, immediately open the drawer, insert test device and close the drawer to continue. The DIGIVAL will time the test development and read the result at the read time. Do NOT open the drawer again until the result is displayed.



STEP 5: Wait for the test completion.

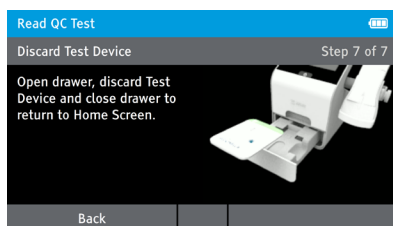
Caution:

- ⚠ **Do NOT open the DIGIVAL drawer during testing. The test is not saved until the completed result is displayed.**
- ⚠ **Never move the DIGIVAL while a test is in progress.**



STEP 6: When a test completes successfully, results are displayed on the screen, with Passed or Failed result. If a test error occurs, 'Invalid' displays. Refer to specific package insert for further details on test result.

If the optional printer is set up, tap **Print** to print the test result. Tap **Home** to return to the home screen or tap **OK** to continue.



STEP 7: Open the drawer and discard the used Test Device. The Test Device can now be removed from the DIGIVAL and disposed of according to federal, state and local regulations.

Caution:

 **Do not reinsert test device once a result has been reported.**

Close the drawer. The display returns to the **Home** screen.

11 Printing Test Results

A printer for the DIGIVAL is optional and may be purchased from Abbott. See Section 20, "Ordering and Contact Information", for printer details and ordering information.

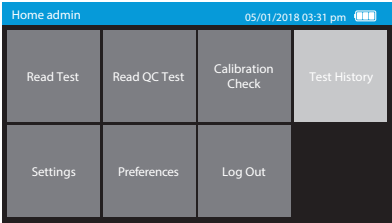
When the printer is connected you can print patient test and QC test results after each test completes, or from the Test History screen.

To configure Auto Print, see **Home>Settings>Test Settings>Auto Print**.

Only connect one printer to the DIGIVAL.

12 Test History

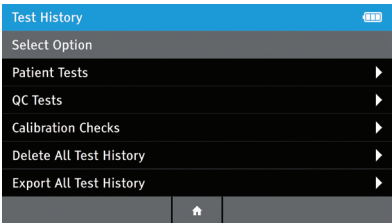
Home>Test History



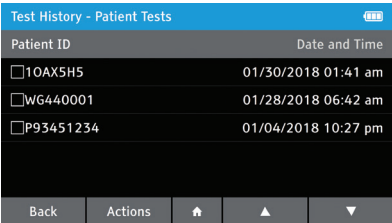
Test results from patients, QC tests and calibration check results are all stored in the DIGIVAL. To view this Information, use the Test History screens.

To view or print Test History, tap **Test History**. A list of options displays.

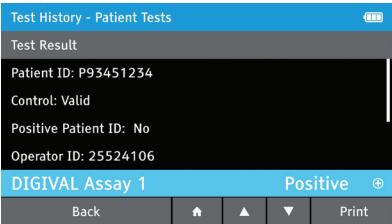
Home>Test History>Patient Tests



Tap **Patient Tests** to view a list of all stored Patient Test Results.



To view individual results, use the up and down arrows or swipe to scroll through the list. To select and view a particular result, tap the checkbox next to the Patient ID and tap **Actions**, then select **View**.



To print a result, ensure the printer is connected, select the particular result, tap the checkbox next to the Patient ID and tap **Actions**, then select **Print**.

Tap **Actions** to Delete All results.

Home>Test History>QC Tests

Tap **QC Tests** to view a list of all stored QC Test Results.

Test History - QC Tests	
Lot Number	Date and Time
<input type="checkbox"/> 9993125	01/30/2018 01:41 am
<input type="checkbox"/> 6832341	01/28/2018 06:42 am
<input type="checkbox"/> 1234567	01/04/2018 10:27 pm
Back Actions Home Up Down	

Tap **Actions** to Delete All QC Test Results.

Use the up and down arrows to scroll through the list. To select and view a particular result, tap the checkbox next to the lot number and tap **Actions** and then tap **View**.

Test History - QC Tests	
QC Test Result	
Test Type: DIGIVAL Assay 1	
Control Type: Positive Control	
Control: Valid	
Operator ID: 25524106	
Positive Control	Passed ✓
Back	Home Up Down Print

To print the result, tap **Print**.

Home>Test History>Calibration Checks

Tap **Calibration History** to view a list of all stored Calibration Check Results.

Test History - Calibration Checks	
Operator ID	Date and Time
<input type="checkbox"/> op1234	01/30/2018 01:41 am
<input type="checkbox"/> op4711	01/28/2018 06:42 am
<input type="checkbox"/> op4242	01/04/2018 10:27 pm
Back Actions Home Up Down	

Tap **Actions** to Delete All Calibration Checks.

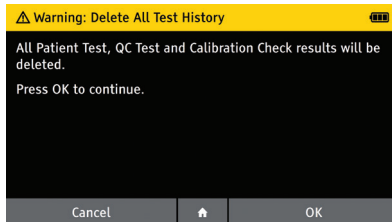
Use the up and down arrows to scroll through the list. To select and view a particular result, tap the checkbox next to the Operator ID and tap **Actions** then tap **View**.

Test History - Calibration Checks	
Calibration Result	
Operator ID: 25524106	
Lot #: 123456	
Exp. Date: 11/01/2018	
01/30/2018 08:37 am	
Calibration Check	Passed ✓
Back	Home Print

To print the result, tap **Print**.

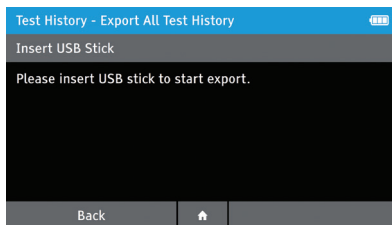
Home>Test History>Delete All Test History (Admin only)

If necessary, you can permanently delete all Patient Test, QC Test and Calibration Check results. Tap **Delete All Test History** and then tap **OK**.



Tap **OK** to permanently delete all results, or tap **Cancel** to exit without deleting.

Home>Test History>Export All Test History



Insert USB memory stick to automatically start export process. Create a password when prompted during the export process.

1. After inserting the USB memory stick, use the keypad to enter the encryption password. Passwords are case-sensitive and must contain at least 1 character. Use the ?123 or Abc keys to switch between the alphanumeric and numeric keypads.
2. Tap OK.
3. Re-enter the password and tap OK.

CREATING A PASSWORD IS REQUIRED TO ACCESS THE DATA CONTAINED IN THE EXPORTED FILE. Abbott will not be able to assist with lost or forgotten passwords as this password is selected by the user.

13 Software Updates

When new tests or software updates become available, the DIGIVAL can be updated by the Admin, using a USB memory stick supplied by Abbott at the time of the software update release. If a middleware system that supports instrument software updates is configured, the DIGIVAL can receive software updates over the network without the need for a USB memory stick. The DIGIVAL prompts the user to insert memory stick or to select the source (if both are present).

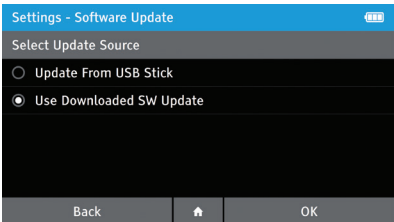
To update the software, tap:

Home> Settings> Administration> Software Update

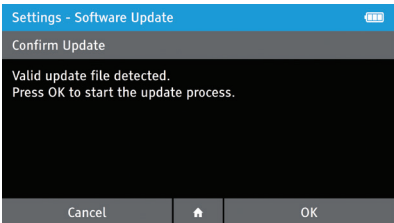
1. Insert the USB memory stick into one of the USB ports on the back of the DIGIVAL. The DIGIVAL looks for an update file.

OR

2. Use downloaded SW Update. This feature allows for instrument management systems to push software updates to the DIGIVAL. This method may be used in place of the USB stick software update feature.



If both a USB memory stick and downloaded SW Update are present, the DIGIVAL prompts the user to select a source for the update.

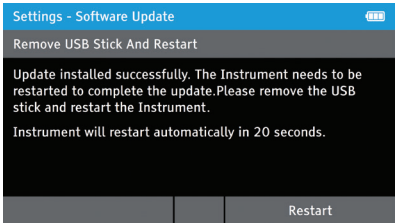


When an update file is validated, Tap **OK** to start the update process.

Caution:

 **Do not remove the USB memory stick during the software update.**

When the update is successful, restart the DIGIVAL, or wait for it to restart automatically.



If unable to complete the software update, please contact Abbott Technical Support. Contact numbers can be found at the end of this User Manual.

14 Care and Cleaning

Cautions:

- ⚠ **Do not disassemble or attempt to repair the DIGIVAL or other accessories as there is a risk of damage to the DIGIVAL. The DIGIVAL does not contain serviceable parts and should be returned for repair. Disassembling the DIGIVAL will also void the warranty.**
- ⚠ **Do not immerse in water or cleaning solutions.**
- ⚠ **Do not clean with soap or other solutions.**

Cleaning the DIGIVAL surfaces and test device tray:

Clean the exterior DIGIVAL surfaces and the test device tray daily, and immediately after possible patient sample contamination.

Acceptable cleaning agents include the following:

- 70% ethanol
- 70% isopropanol
- 10% bleach solution on a damp, lint free cloth

DO NOT use commercially available 10% bleach wipes for cleaning the DIGIVAL.

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

Clean surrounding bench area. Clean DIGIVAL and surrounding areas immediately after possible patient sample contamination.

15 Accessories

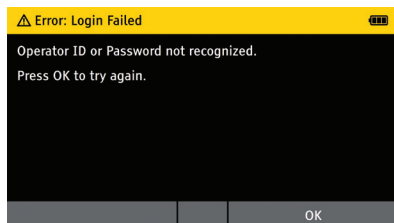
Accessories for use with the DIGIVAL can be ordered separately.

To order, see Section 20, “Ordering and Contact Information.”

16 Errors and Warnings

This section provides troubleshooting steps for specific error and warning codes. If the warning or error persists after you have followed the instructions on the screen, contact Abbott Technical Support. Contact numbers can be found at the end of this user manual.

Example Screen



16.1 Errors

E.1 Calibration Check Required

Error: Calibration check required to continue.

Action: Perform a calibration check to continue. See Section 6, "DIGIVAL Calibration."

E.2 Login Failed

Error: Login failed.

Action: Tap **OK** and enter a correct operator ID and password. If the error persists, contact the Admin or contact Abbott Technical Support.

E.3 Operator ID in Use

Error: Operator ID is already in use.

Action: Tap **OK** to enter a different operator ID. If the error persists, contact Abbott Technical Support.

E.4 Operator ID Invalid

Error: Operator ID invalid.

Action: Tap **OK** to enter a different Operator ID. Operator ID must be 2 to 20 characters long, contain only alphanumeric characters and have no spaces. If the error persists, contact Abbott Technical Support.

E.5 Operator Not Certified

Error: Operator is not certified to run this type of test.

Action: Contact instrument administrator.

E.6 Drawer Open

Error: Drawer is open.

Action: Close the drawer to continue. If the error persists, contact Abbott Technical Support.

E.7 Test Device ID Invalid

Error: Test device ID invalid.

Action: Check foil pouch to ensure barcode was scanned or manually entered correctly. Ensure that the test is supported by the current version of the DIGIVAL. To check software version tap **Home> Preferences> About**. The software version will indicate which test types are supported. Tap **OK** to try again. If the error persists, contact Abbott Technical Support.

E.8 Test Type Not Supported

Error: Test type not supported by current software version.

Action: Check if the software is up to date, or tap **OK** to try again with a supported test device. To check software version tap **Home> Preferences> About**. The software version will indicate which test types are supported. If problem persists contact Abbott Technical Support.

E.9 Test Device Expired

Error: Test device has expired.

Action: Tap **OK** and try again using an in-date test device. If problem persists contact Abbott Technical Support.

E.10 Tray Barcode Read Failure

Error: Tray barcode could not be read.

Action: Open drawer, check tray barcode is not obscured and close drawer to try again. If problem persists contact Abbott Technical Support.

E.11 QC Test Required

Error: QC test required to continue.

Action: The DIGIVAL's QC policy requires a positive and negative QC test for this test type and lot number to be completed in order to continue. Please complete a positive and negative QC test to continue.

E.12 Incorrect Tray

Error: The correct tray is required.

Action: Open drawer, insert the correct tray and test device. Close drawer to continue. If problem persists contact Abbott Technical Support.

E.13 Patient ID Invalid

Error: Patient ID Invalid.

Action: Patient ID must be 2 to 20 characters long, contain only alphanumeric and some special characters, such as # () * /\ and have no spaces. Tap **OK** to try again. If the error persists, contact Abbott Technical Support.

E.14 Test Device QR Code Read Failure

Error: Test device QR code read failure.

Action: Open drawer, check test device and orientation are correct, QR code is not obscured and close drawer to continue. If error persists please contact Abbott Technical Support.

E.15 Test Device ID Mismatch

Error: Foil pouch barcode and test device QR code do not match

Action: Open drawer, insert the test device from the scanned foil pouch and close drawer to continue. Ensure the test device is from the foil pouch which was scanned. If problem persists, contact Abbott Technical Support.

E.16 Test Device Present

Error: Test device is present in the drawer.

Action: Open drawer, remove the test device and close drawer to continue. If the error persists, contact Abbott Technical Support.

E.17 Calibration Check Card Expired

Error: Calibration Check Card Expired.

Action: Open drawer, replace with an in-date Calibration Check Card and close drawer to continue.

E.18 Calibration Check Card QR Code Read Failure

Error: Could not read Calibration Check Card QR Code.

Action: Open drawer, ensure tray is removed to expose Calibration Check Card. Ensure Calibration Check Card is present and positioned correctly, QR code is not obscured and close drawer to continue. If problem persists replace Calibration Check Card and try again. If the error persists, contact Abbott Technical Support.

E.19 Password Invalid

Error: Password is invalid.

Action: Tap **OK** to try again. Passwords are case-sensitive and cannot contain spaces. Passwords must be 4–20 characters long. If the error persists, contact Abbott Technical Support.

E.20 Password Mismatch

Error: “Password” and “Password Confirmation” do not match.

Action: Tap **OK** to try again. Make sure that both passwords match. Passwords are case-sensitive. If the error persists, contact Abbott Technical Support.

E.21 Update File Not Found

Error: No update file was found on the USB memory stick.

Action: Please try again with a USB memory stick containing an update file. If the error persists, contact Abbott Technical Support.

E.22 Network Error

Error: Network is unreachable.

Action: Check the cable and network configuration and try again. If the error persists, contact Abbott Technical Support.

E.23 Test Upload Failed - Server

Error: A server communication error occurred, and Patient Test results could not be uploaded.

Action: Check middleware configuration and try again. If the error persists, contact Abbott Technical Support.

E.24 Test History Export

Error: Test History export failed.

Action: Check that the USB memory stick is connected, formatted correctly and that it has enough free memory. If the error persists, contact Abbott Technical Support.

E.25 Operator Limit Reached

Error: Operators cannot be created because the maximum operator limit has been reached. The maximum number of operators is 1000.

Action: Delete obsolete operators in order to create new operators. If the error persists, contact Abbott Technical Support.

E.26 Log Export Failed

Error: Log export failed.

Action: Check that the USB memory stick is connected, formatted correctly, and that it has enough free memory. If the error persists, contact Abbott Technical Support.

E.27 Last Name Invalid

Error: The patient's last name is invalid.

Action: Tap **OK** to try again. Last name must be 2-20 characters long. Field names are case sensitive and must be alpha numeric. If the error persists, contact Abbott Technical Support.

E.28 Date of Birth Invalid

Error: Date of birth invalid.

Action: Date of birth must contain only numeric characters separated by "/" and have no spaces. The correct format is mm/dd/yyyy. If error persists, contact Abbott Technical Support.

E.29 Drawer Open

Error: If a test is being run in Walk Away mode and the user opens the drawer, this error will appear.

Action: Close drawer to continue.

E.30 Assay Add Error

Error: Assay can not be added.

Action: Check Product Insert to see if the assay is supported for this instrument. If error persists, contact Abbott Technical Support.

E.31 QC Lot Number Invalid

Error: QC Lot Number must be 2 to 20 characters long, contain only alphanumeric characters and have no spaces.

Action: Tap **OK** and try again.

E.32 Operator Import Failed

Error: Operator Import failed to upload.

Action: Check if USB Memory Stick is connected and has an operator list in the correct format.

E.33 Operator Export Failed

Error: Operator Export Failed.

Action: Check if USB Memory Stick is connected, formatted correctly and has enough free memory.

E.34 Multiple Update Files Found

Error: Multiple update files were found on the USB Memory Stick.

Action: Try again with a USB Memory Stick containing an update file.

Note: *For error codes not found in the user manual, please contact Abbott Technical Support.*

E.35 Synchronization Failed - Network

Error: Network can not be reached.

Action: Check cable and network configuration and try again.

If error persists, contact Abbott Technical Support.

E.36 Synchronization Failed - Server

Error: Sync failed due to server communication error

Action: Contact your administrator.

E.37 Positive Patient ID Failed - General

Error: System failed to match Patient ID entered with Patient ID information in system

Action: Check ID and re-enter or re-scan. If error persists, check information in Hospital Information System that manages patient records.

E.38 Assay Lot Number is Locked Out

Error: The lot entered has been locked out by the administrator.

Action: Tap **OK** to try again using a Test Device with a different lot number.

E.39 Patient ID Lockout

Error: The patient ID is unknown.

Action: Tap **OK** and try again.

E.40 Patient Information Lockout

Error: The information for a specific patient ID is incorrect.

Action: Tap **OK** and enter correct patient ID.

E.41 Input Invalid

Error: The Threshold must be greater than 0 and less than 1000 (for Rule under QC Lot Management).

Action: Tap **OK** to try again.

E.42 Barcode Invalid

Error: Barcode is not valid.

Action: Verify that pouch barcode was scanned or manually entered correctly.

Tap **OK** to try again.

E.43 Lot ID Add Failed

Error: Failure to Add Lot to the Blacklist.

Action: Tap **OK** to try again. If problem persists, contact Abbott Technical Services.

E.44 Lots Import Failed

Error: Failure to import Lots from USB memory stick.

Action: Check if USB is connected, formatted correctly, and has enough free memory.

E.45 Lots Exports Failed

Error: Failure to export Lots from USB memory stick.

Action: Check if USB is connected, formatted correctly, and has enough free memory.

16.2 Critical Errors

CE.1 Test Device Read Failure

Error: Test device read failure.

Action: QC test is invalid. Restart QC test procedure using new test device.

CE.2 Calibration Check Card Read Failure

Error: Calibration Check Card read failure.

Action: Close drawer and restart Calibration Check Card procedure. Refer to Section 6, "DIGIVAL Calibration" for instructions.

CE.3 DIGIVAL™ Instrument Fault

Error: DIGIVAL Instrument Fault.

Action: Restart DIGIVAL and try again. If the error persists, make note of the fault code displayed and contact Abbott Technical Support.

CE.4 Update Failed

Error: Software update failed.

Action: Please remove USB memory stick and restart update process. If problem persists, please contact Abbott Technical Support.

16.3 Warnings

W.1 Memory Almost Full

Warning: Memory almost full.

Action: Export test history to USB memory stick or tap **OK** to continue. You will need to complete the export and then delete all tests in the memory. See Section 12, "Test History."

W.2 Memory Full

Warning: Memory is full. This warning applies for Patient Tests and QC Tests.

Action: Export test history to USB memory stick or tap **OK** to overwrite the oldest test.

W.3 Auto Log Out

Warning: Operator will be automatically logged out.

Action: Tap **Cancel** to return to home screen.

W.4 DIGIVAL™ Restart Required

Warning: The DIGIVAL will restart to activate new language setting.

Action: Tap **OK** to continue. Tap **Cancel** to stop activation of new language. Tap **Home** to stop activation of new language and return to home screen.

W.5 DIGIVAL™ Restart Required

Warning: The DIGIVAL will restart to activate new assay.

Action: Tap **OK** to continue.

W.6 Delete All Test History

Warning: All patient test, QC test and calibration check results will be deleted.

Action: Tap **OK** to delete all history or **Cancel** to stop test history deletion. Tap **Home** to stop test history deletion and return to home screen. **Note:** *Once test history is deleted, results cannot be retrieved.*

W.6.1 Delete All Patient Tests

Warning: All Patient Test results will be deleted.

Action: Tap **OK** to delete all history or **Cancel** to stop test history deletion. Tap **Home** to stop test history deletion and return to home screen. **Note:** *Once test history is deleted, results cannot be retrieved.*

W.6.2 Delete All QC Tests

Warning: All QC test results will be deleted.

Action: Tap **OK** to delete all history or **Cancel** to stop test history deletion. Tap **Home** to stop test history deletion and return to home screen. **Note:** *Once test history is deleted, results cannot be retrieved.*

W.6.3 Delete All Calibration Checks

Warning: All Calibration Check test results will be deleted.

Action: Tap **OK** to delete all Calibration Check results or **Cancel** to stop deletion. Tap **Home** to stop deletion and return to home screen. **Note:** *Once Calibration Check results are deleted, results cannot be retrieved.*

W.7 Factory Reset

Warning: If you tap **OK**, all test results will be deleted and DIGIVAL settings will be reset to factory default.

Action: Tap **OK** to continue or **Cancel** to stop factory reset. Tap **Home** to stop factory reset and return to home screen. **Note:** *Once test history is deleted, results cannot be retrieved.*

W.8 Calibration Check Card Expiring

Warning: Calibration Check Card will expire on <<DATE>>.

Action: Open drawer, replace with an in-date Calibration Check Card and close drawer to try again. Refer to Section 20, "Ordering and Contact Information" for ordering information.

W.9 Test Cancellation Attempt

Warning: This warning will appear during Walk Away mode if the user cancels the test while the timer is running.

Action: Tap **Yes** to cancel or **No** to return to the test.

W.10 Import All Operators

Warning: Importing new operators will delete all existing operators and passwords.

Action: Tap **OK** to continue.

W.11 Patient ID unknown

Warning: This warning will alert user that Patient ID is not recognized.

Action: Tap **OK** to continue and **Back** to re-enter.

W.12 Patient Information is Incorrect

Warning: This warning alerts the user that the Patient ID is not correct.

Action: Tap **Yes** to enter patient information or **No** to enter a different ID.

W.13 QC Test Recommended

Warning: The QC policy recommends a positive and negative ID test for test type.

Action: Tap **OK** to continue.

W.14 Low Battery

Warning: Low Battery

Action: Connect to power source

Tap **OK** to Continue.

W.15 Power Off Confirmation

Warning: This warning will appear to confirm that user intends to turn instrument off.

Action: Tap **No** to continue using instrument or **Yes** to turn power off.

17 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



Biological risk



Caution, consult accompanying documents



Waste electrical and electronic equipment directive compliant



Serial number



In Vitro diagnostics



Authorized Representative in the European Community



CE mark



Manufacturer



Keep away from sunlight



On-Off power button



Importer



Device NOT for self-testing

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 of 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.

18 DIGIVAL™ Specifications

18.1 DIGIVAL™

DIGIVAL™	
Color Touch Screen	4.3"
Communications	<p>Automatic upload of test result (to a data management system) after completion of the reading process.</p> <p>Manual upload of test results from memory.</p> <p>Contact Abbott Technical Support for further information.</p>
Data storage	<p>1000 patient test results</p> <p>100 QC test results</p> <p>50 Calibration Check test results</p> <p>Memory allows user to review and print results until the results are uploaded to a data management system.</p>
Power Supply	<p>12V DC from external AC/DC supplied plug pack</p> <p>DC current consumption: 12V DC, 3.0 Amps</p>
Dimensions	125 mm W x 195 mm H x 160 mm D
Approximate Weight	1.5 kg
Operating Environment	<p>Indoor Use</p> <p>Lux levels: 100-3500 Lux</p> <p>Altitude: 0-2000m</p> <p>15°C to 30°C (50°F to 86°F)</p> <p>20% to 80% RH (non-condensing)</p> <p>IP20 Type 1</p>
Storage	<p>15°C to 30°C (50°F to 86°F)</p> <p>20% to 80% RH (non-condensing)</p> <p>Altitude: 0-2000m</p>

18.2 Power Supply

12V Power Supply	
Rated input voltage:	100-240VAC
Rated input frequency:	50/60Hz
Rated input current:	1.2 Amps
Operating environment:	As per DIGIVAL
Storage environment:	As per DIGIVAL
Output voltage:	12V DC
Output current:	3.0-3.5 Amps

19 Warranty (EN)

Limited 2 Year Warranty

Use of the DIGIVAL

The DIGIVAL is a small bench top instrument to be used in conjunction with Abbott rapid assays. It is intended to be used for professional and laboratory use only.

DIGIVAL will capture, interpret and transmit results of select Abbott rapid lateral flow tests and can be used in the laboratory and point of care settings. It is a camera based instrument that will detect the presence and identity of a completed lateral flow assay, analyze the intensity of the test and control line and display the results (positive, negative or invalid) on a display screen.

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.**

Warranty

Abbott warrants the DIGIVAL (excluding disposable or consumable supplies) against defects in materials and workmanship for two years from the date of purchase. If Abbott receives notice of such defects during the two-year warranty period, Abbott shall, at its option, either repair or replace products which prove to be defective. With respect to software or firmware, if Abbott receives notice of defects in these products during the two-year warranty period, Abbott shall repair or replace software media and firmware which does not execute their programming instructions due to such defects. Abbott does not warrant that the operating of the software, firmware or hardware shall be uninterrupted or error free. If Abbott is unable to repair or replace any DIGIVAL to a condition as warranted, Buyer shall be entitled to a refund of the purchase price upon return of the defective DIGIVAL to Abbott.

Please contact Abbott Technical Support prior to returning any defective DIGIVAL. Refer to Ordering and Contact Information section of the user manual for additional information.

Limitations of Warranty

The foregoing warranty shall not apply to defects resulting from: (1) Improper or inadequate maintenance by Buyer or an unauthorized person, (2) Using accessories and/or consumables that are not approved by Abbott, (3) Unauthorized repairs, modifications, misuse, or damage caused by Buyer or an unauthorized person, or (4) Operating the DIGIVAL outside of the environmental specifications of the product.

THE WARRANTY SET FORTH ABOVE IS EXCLUSIVE AND NO OTHER WARRANTY, WHETHER WRITTEN OR ORAL, IS EXPRESSED OR IMPLIED. ABBOTT SPECIFICALLY DISCLAIMS THE IMPLIED WARRANTIES OF MERCHANTABILITY, NONINFRINGEMENT, AND FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT WILL ABBOTT BE LIABLE FOR ANY INCIDENTAL, INDIRECT, SPECIAL, CONSEQUENTIAL, OR PUNITIVE LOSS OR DAMAGES IN ANY WAY RELATED TO THE DIGIVAL, EVEN IF ABBOTT IS AWARE OF THE POSSIBILITY OF SUCH CLAIM OR DAMAGES.

20 Ordering and Contact Information

20.1 Reorder numbers:

DIGIVAL: LFR-000 (OUS) ① +1 321 441 7200

DIGIVAL: LFR-024 (US) ① +1 877 441 7440

Calibration Check Card Pack: LFR-003

DIGIVAL Tray 1 Pack: LFR-004

Martel Thermal Printer: MCP1810395

Printer Paper: 20001584 (GP25)

Abbott USB Memory Stick: EQ004003

Opticon Barcode Scanner: L22XWU1-200

20.2 Abbott Contact Information

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

US

+1 888 735 5317 ts.scr@abbott.com

Africa, Russia, CIS

+44 161 483 9032 EME.TechSupport@abbott.com

Asia Pacific

+61 7 3363 7711 AP.TechSupport@abbott.com

Canada

+1 800 818 8335 CANproductsupport@abbott.com

Europe & Middle East

+44 161 483 9032 EME.TechSupport@abbott.com


Latin America

+57 601 482 4033 LA.TechSupport@abbott.com

Summary of Introduced Modifications Since Last Revision:

Section	Modification
Intended Use	Add statement “For professional use only. Not for self-testing. For near-patient indications, refer to each specific Abbott Rapid Test package insert.”
Warnings and Safe Use	Add Caution regarding emissions characteristics.
DIGIVAL Customer Cybersecurity Responsibilities	Add new section.
Symbols Glossary	Symbols added for Importer and Device NOT for self-testing. Replaced Biological Hazard symbol with Biological Risk symbol. Deleted RoHS symbol.
Symbols Glossary	Add Emissions and Immunity Compliance information.
Information on Disposal for Users of WEEE	Add new section.
DIGIVAL Specifications	Add IP rating.
Ordering and Contact Information	Edit printer paper reference to 20001584 (G25).
Abbott Contact Information	Update Latin American telephone number to read: +57 601 4824033. Update the email address contacts to read: -AP.TechSupport@abbott.com (APAC) -LA.TechSupport@abbott.com (LATAM) -EME.TechSupport@abbott.com (Africa/Russia/Europe/Middle East)
Summary of Introduced Modifications Since Last Revision	Add new section and summary.
Back Page	Update manufacturer’s website address, Add ‘Device NOT for self-testing’ symbol, update copyright date. Deleted TUV certified symbol. Updated the TUV symbol.



 **Abbott Diagnostics Scarborough, Inc.**
10 Southgate Road
Scarborough, Maine 04074 USA
www.globalpointofcare.abbott



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