Endosafe®
nexgen-pts

SOFTWARE MANUAL

Portable Test System with Nexgen 11.1

charles river

PIPTS150SW.11.1-00

Contents

1 DOCUMENT CONVENTIONS

The following conventions are used throughout this document to highlight specific information:

Caution – Warns the user that failure to avoid a specific action could result in physical harm to the user or the hardware.

Caution – Warns the user of a potential shock situation.

Informational – Advises of important information for completing the task.

2 ABBREVIATIONS

Abbreviations used in this manual	
DHCP	Dynamic Host Configuration Protocol
DST	Daylight Savings Time
EU	Endotoxin Unit **(Note: 1EU is equivalent to 1IU [International Unit])**
IP	Internet Protocol
LAL	Limulus Amebocyte Lysate
LAN	Local Area Network
LRW	LAL Reagent Water
MAC Address	Media Access Control Address
.pdf	Portable Document Format
PTS	Portable Test System
rCR	Recombinant Cascade Reagent
SSID	Service Set Identifier
USB	Universal Serial Bus
Wi-Fi	The standard wireless local area network (WLAN) Technology for connecting computers and other electronic devices to each other and to the internet.
WLAN	Wireless Local Area Network
WPA-2	WPA-2 (Wi-Fi Protected Access)

3 WARRANTY AND SERVICE PROGRAMS

3.1 Warranty With Purchase

For detailed information regarding the warranty of the Endosafe® nexgen- PTS™ instrument, please see our Terms and Conditions.

3.2 Service Programs

For information regarding our service programs for the Endosafe® nexgen- PTS™, contact us at Endosafe-Support@crl.com.

3.3 Additional Information

All warranty and service options are subject to the Terms and Conditions and procedures specified in the Service Agreement. For answers to questions about any of these components for the Endosafe® nexgen-PTS™ instrument, or for additional product information, please contact our Technical Services Department:

United States:

1023 Wappoo Road, Suite 43B

Charleston, SC 29407

(843) 402-4900

Endosafe-Support@crl.com

Europe:

Greenogue Business Park

649 Jordanstown Ave

Jordanstown, Rathcoole, Co.

Dublin, D24 NF21 Ireland

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4 INTRODUCTION TO THE ENDOSAFE® NEXGEN-PTS™ INSTRUMENT

The Endosafe® nexgen-PTS™ instrument is the second generation single- cartridge instrument from Charles River Laboratories. The instrument contains an incubating system, an internal computer, and a touch screen to access various menus. It is a rapid, point-of-use handheld spectrophotometer that utilizes disposable cartridges for accurate, convenient, and real-time endotoxin, Gram identification, and Beta-glucan testing. The instrument provides quantitative limulus amebocyte lysate (LAL) and recombinant cascade reagent (rCR) test results in approximately 15 minutes. For further information on the instrument, please refer to the Endosafe® nexgen-PTS™ Hardware Manual. For further information pertaining to the cartridge test procedures, please refer to the Endosafe® nexgen-PTS™ Assay Guides.

The nexgen-PTS™ has the ability to store thousands of results, users, samples, and accessories in its internal storage. As noted above, it has an internal computer with its own internal memory.

5 NOTIFICATION PANEL

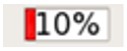
This section explains the meanings of the various notifications encountered in the notification panel when using the Endosafe® nexgen-PTS™ instrument.

Notification Panel

Screen	Icon	Description
		Battery Power notifications will display in the top right-hand corner.
		The Wi-Fi icon will display when a Wi-Fi connection has been set up, provided it is available on the unit. See section 8.5.2.2.
	17 Sep 2020 2:13 PM	The Current Date and Time will display at the top of the screen. See section 8.5.3 for setting the date and time.
		The Ethernet icon will display when a wired network connection exists. See section 8.5.2.1.
	user	If User Management is On, the current logged-in user account will display.
	37.0 °C	Temperature of Internal Testing Chamber will update as the internal temperature changes. The temperature of the internal testing chamber will increase after the initial boot up of the instrument as the instrument warms up.
		This icon will appear when the system recognizes a USB device is plugged into the system.

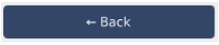
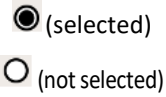
Power Notification

Icon	Description
	**External AC Power icon** – Instrument is charging when this icon is displayed. If the **External AC Power** icon is not displayed, then the instrument is operating on battery power and is not charging.
	**Battery Power icon green** – Battery voltage is sufficient for operation. The **Battery Power** icon will update during use, displaying a battery power gauge (percent charge remaining).

	**Battery Power icon red** – Battery voltage is low, and the instrument should be charged. The **Battery Power** icon will display a battery power gauge (percent charge remaining) when it gets below 25%. If the AC Power icon is not displayed, then the instrument is operating on battery power and is not charging. The system will notify the user with a prompt that it should be connected to **AC Power** if the level gets below 10%. It will also notify the user once the battery level is so low that the system can no longer run on battery and will begin a shutdown two minutes after this notification.

6 NAVIGATION

Power Notification

Button	Function
	**123 Button** – When pressed, it displays the **Numeric Characters Keyboard** (123 button will replace the **ABC** when **Alpha Keyboard** is launched).
	**ABC Button** – When pressed, it displays the **Alpha Characters Keyboard** (allows access to **Numeric Keyboard** and **Special Characters Keyboard**).
	**Menu Button** – Pressing the **Menu** key will toggle between the running sample test functions and main menu functions.
	**Home Button** - When pressed, it returns the user to the main menu screen.
	**Previous Page Button** – Allows the user to navigate to the previous page when multiple pages are available. If multiple pages are not available, this button will be inactive.
	**Next Page Button** – Allows the user to navigate to the next page when multiple pages are available. If another page is not available, this button will be inactive.
	**Back Button** – When pressed, it returns the user to the previous screen.
	**Selected/Not Selected Radio** Buttons – Displays with corresponding text to enable or disable an option or function. When the button is selected, it will display full. When the button is not selected, it will display empty.
	The **Back** button will take you to the previous screen. It may need to also be pressed several times in order to go back to the **Main Menu** or **Insert Cartridge** screen depending on what page the user is on.

7 KEYBOARDS

This section explains the keyboards and any special characters the user will encounter when input into an open field is required.

The Endosafe® nexgen-PTS™ instrument is configured with:

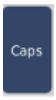
- An **Alpha Characters Keyboard** (ABC…)
- A **Numeric Characters Keyboard** (123…)
- A **Special Characters Keyboard** (@#$...)
- The **Alpha Characters Keyboard** and **Numeric Characters Keyboard** can be displayed by selecting the corresponding Keyboard button located at the bottom of the screen (indicated by **ABC** or **123**). The **Special Characters Keyboard** is displayed using the **Special Characters Keyboard** button (**!?**) from the **Alpha Characters Keyboard (lower case)**.

Alpha Characters Keyboard

Numeric Characters Keyboard

Special Characters Keyboard

Keyboard Symbols

Button	Function
	**Clear** – Deletes **ALL** information typed in a field).
	**Backspace** – Deletes information in a field one character at a time).
	**Enter** – Activates next available field.
	**Close** – Hides the keyboard from view.
	**Caps** – Switches the **Alpha Characters Keyboard** between UPPERCASE letters and lowercase letters.
	**Special Characters Keyboard** (button) – Switches back to the **Special Characters Keyboard** when the **Alpha Characters Keyboard** is active.
	**Alpha Characters Keyboard** (button) - Switches back to the **Alpha Characters Keyboard** when the **Special Characters Keyboard** is active.
	For most fields, when the field is selected, the instrument will automatically display a keyboard to allow for user input. If the keyboard is not present and is needed, select the **ABC** or the **123** button to display the keyboard.

8 MENU

This section describes the menu and the functions and options that are accessible from the menu. The Menu is accessed by selecting the Menu button at the bottom of the screen.

Note: If User Management is enabled, some menus may not be accessible to the user, depending on their role and permissions assigned to that user.

Page 1 of Main Menu

Menu

Screen	Icon	Description
		**Sample Database** – This icon allows a user to navigate to the sample database. It allows a user to input sample information, such as **Sample Name, Dilution/ Concentration**, and **Endotoxin Limit**. A user can also preload the next test with sample information through this menu.
		**Accessory Database** – This icon allows a user to navigate to the accessory database. It allows users to input accessories such as pipettors, LAL reagent water, etc. that can be used to perform an assay.
		**Reports** – This icon allows a user to navigate to view all completed assays. Users can print reports or graphs and export reports or assay audit trails through this menu.
		**Audit Trail** – This icon allows users to view the system audit trail, as well as export, backup, and restore the audit trail.
		**Administration** (system settings) – This icon allows users to navigate to the settings on the instrument.
		**Shutdown** – This icon can be used to shut down or restart the instrument. **Note: The instrument should always be shutdown via this menu under normal circumstances when used as a standalone instrument.**

To navigate to the second page, select **Next Page.**

Menu

Screen	Icon	Description
		**USB Devices** – This icon allows users to view and connect to USB devices. This menu allows a user to save logs to a USB device or upgrade software from a USB device. **Note: Only FAT32 USB devices are compatible with the nexgen-PTS™.**

8.1 Sample Database (For Use with Endotoxin and Beta-Glucan Test Cartridges Only)

This section describes the process for editing, reviewing, and adding information to the **Sample Database**. To access the Sample Database, select the Sample Database icon from the **Menu** screen.

The Endosafe® nexgen-PTS™ instrument stores a sample database consisting of Sample Name, Dilution, Endotoxin Limit, and Units. If User Management is On, access to certain sample database functions will be limited to a user with appropriate permissions. All users can view the sample database and select sample information with which to load a test. The sample database can be used to pre-load samples in order to streamline the testing process. When pre- loading a test with sample information, all information in the sample database is loaded for the next test so the only sample information the user will need to enter is the sample lot number for the next test.

If using Charles River's Cortex™ Software, the sample database can be updated in Cortex and sent to connected nexgen-PTS™ instruments. See the Cortex Client Manual for more information.

Note: If User Management is On, samples can only be created, edited, or deleted by a user with appropriate permissions

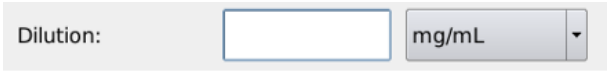
8.1.1 *Creating a New Sample in The Sample Database*

This section describes how to create a new sample in the sample database.

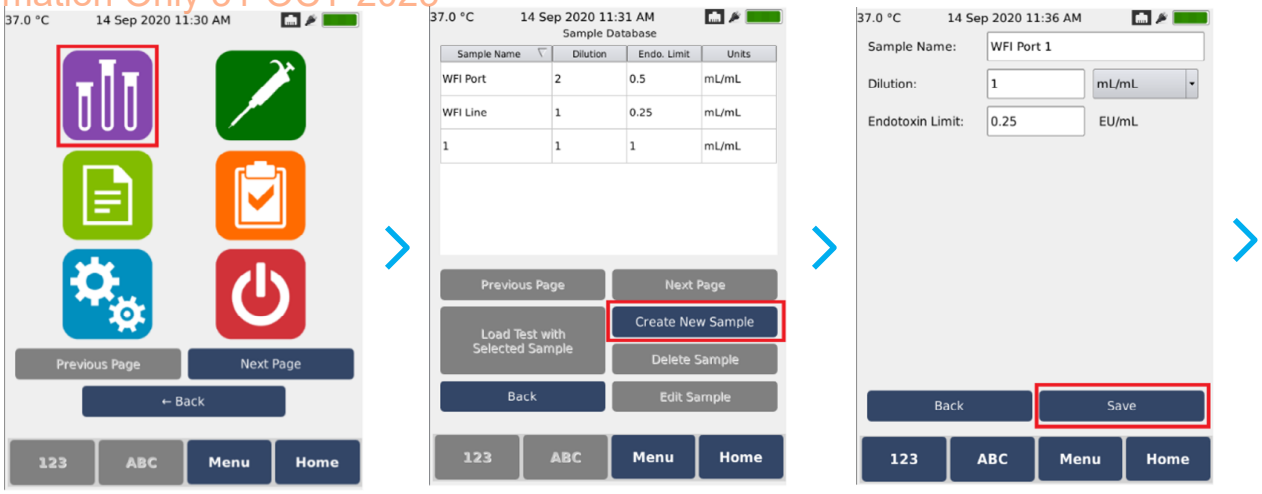
1. Select the **Create New Sample** button.
2. Enter information for the **Sample Name** (character limit = 120 characters).
3. Enter the **Dilution and Correct Units** from the drop-down menu.
    a. From the drop-down box next to the Dilution field, select mL/mL, L/mL, g/mL, mg/mL, µg/mL, ng/mL, device/mL, or Unit/mL. The Endotoxin units will automatically change depending on Dilution units. Limited to nine (9) decimal places

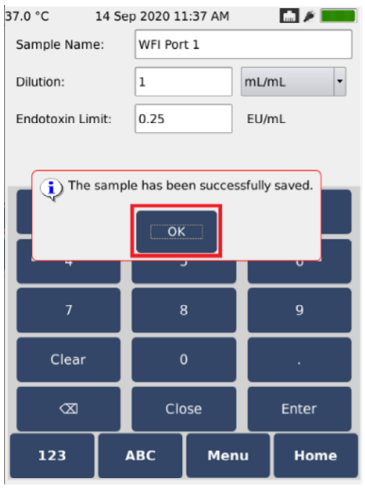
    b. When choosing device/mL, the value is entered as a ratio in two fields (i.e., **2:3** device/mL).

    c. All other dilutions or concentrations are a single-value ratio compared to one or numerical concentration unit per mL (i.e., 1:**100** mL/mL or **1.5** mg/mL).



4. Enter the **endotoxin limit, if necessary**. The units will update based on the dilution units (EU/Dilution Unit) (i.e., EU/mL, EU/mg, EU/Unit, EU/ device, etc.).
    a. When creating samples for Beta-glucan cartridges, the endotoxin limit can be left blank or value on report will be converted to pg per dilution unit (i.e., pg/mL, pg/mg, pg/Unit, pg/device, etc.).
5. Select the **Save** button when finished. A prompt will display, “The sample has been successfully saved”. Press **OK.**



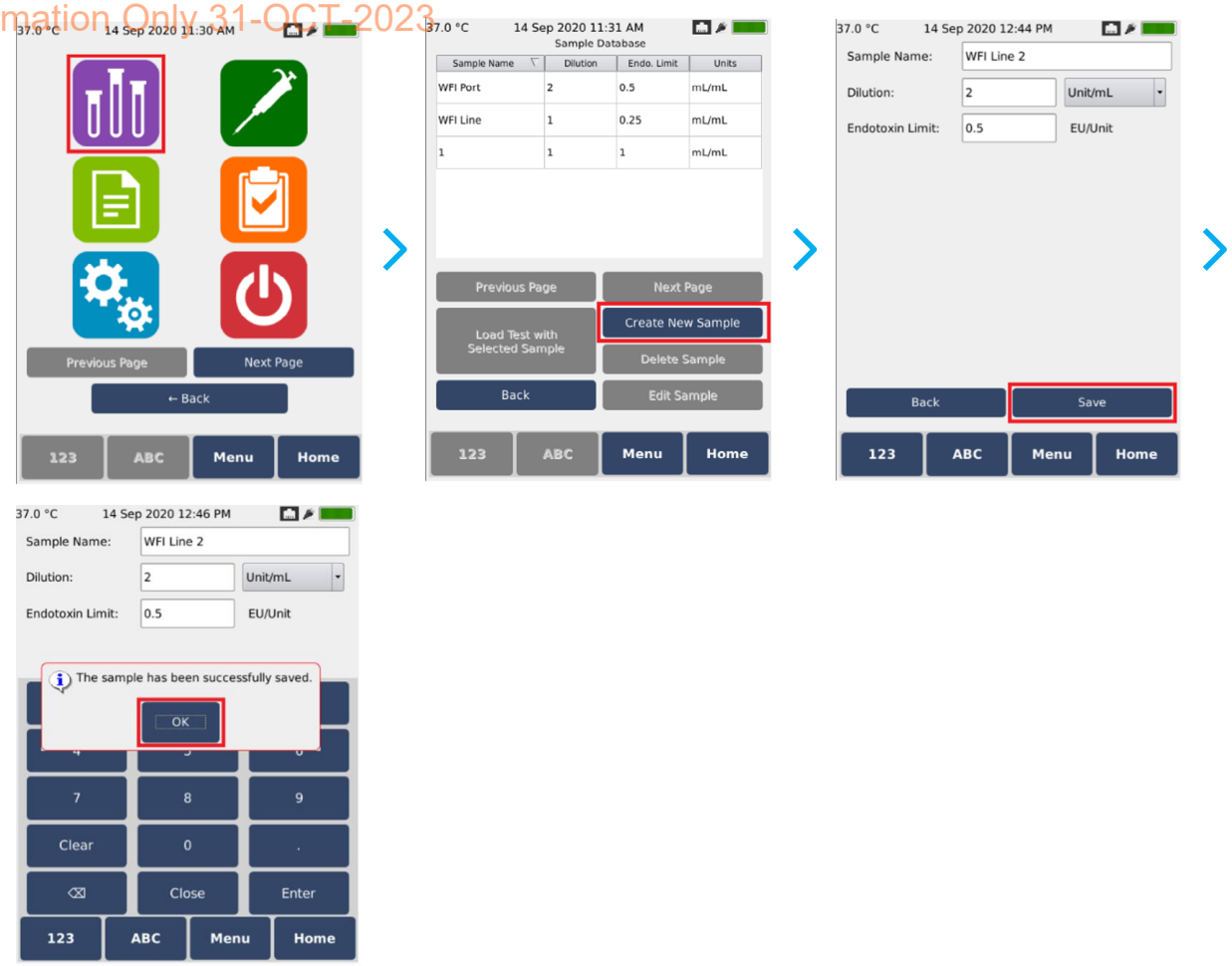


	When setting up the sample database, the Endotoxin Limit field can be left blank. If the field is left blank, the user can still input a limit in this field while running the sample. The required fields are Sample Name and Dilution.

8.1.2 *Editing the Sample Database*

This section describes how to modify the sample database when the database is populated with existing samples.

1. Select the sample database row to edit.
    a. The **Previous Page** and **Next Page** buttons can be used to navigate through the sample database on the instrument.
2. Select the **Edit Sample** button.
3. Select the field that needs to be edited *(Sample Name, Dilution, or Endotoxin Limit)*. See section 8.2.1 for details on each field.
4. Select the **Save** button when complete. A prompt will display, *"The sample has been successfully saved"*. Press **OK.**

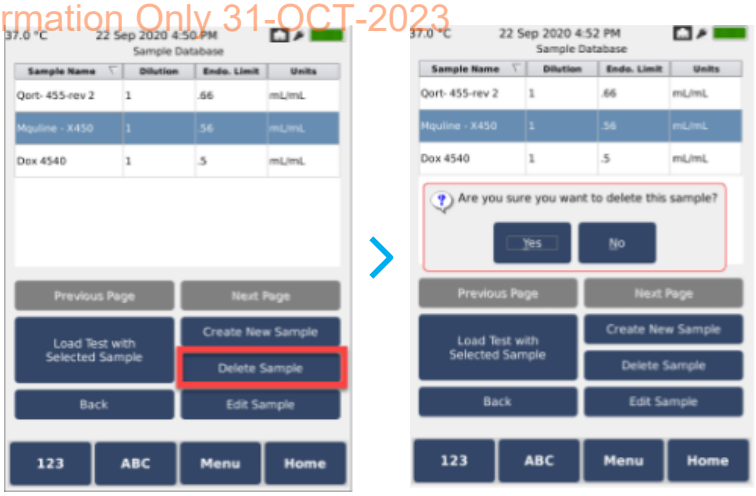


8.1.3 *Deleting a Sample from Database*

This section outlines how to delete a sample from the Sample Database, the sample cannot be restored once deleted.

1. Select the sample database row to delete.
    a. The **Previous Page** and **Next Page** buttons can be used to navigate through the sample database on the instrument.
2. Select the **Delete Sample** button.
3. A prompt will display, “Are you sure you want to delete this row?” Press **Yes** to delete the row or **No** to cancel. **Note: Deleted samples cannot be recovered**.

Deleting a Sample from Database



8.1.4 *Loading a Test with Selected Sample*

All user accounts can load a test from the sample database. This feature will load a sample for the next test to be run. This means that if a cartridge is currently running and a sample is selected from the sample database to be loaded for the next test, the sample information will populate the next assay to be run. If a user selects a sample from the database and then decides to load a different sample, this will overwrite the current sample information.

If User Management is **On**, a user must be logged in to populate the next test with sample information. Until the cartridge is at the Add Sample screen, it is considered the next test. Once the assay is started, the sample information can be updated at any time either through the **Sample Database** screen or the sample screen during assay setup.

1. Select the sample database row to load a sample for the next test.
    a. The **Previous Page** and **Next Page** buttons can be used to navigate through the sample database on the instrument.
2. Select the **Load Test with Selected Sample** button.
3. A prompt will display, *"The values from this sample have been loaded for the next test"*. Press **OK**.
4. When setting up the next test, the instrument will pre-load the selected sample information into open fields.

Loading a Test with the Selected Samples

	Note: The sample information will load at the beginning of the next test with the information of the selected sample. It will not replace information for an assay in progress. If a test has not yet gotten to, or beyond, the Add Sample screen, then hitting Load Test with Selected Sample will update that specific test.

8.1.5 *Backup and Restore Sample Database*

From the Sample Database menu, press the Backup/Restore button. A menu will appear, allowing the user to backup or restore the Sample Database to or from a USB device or a connected network.

	Backup/Restore to/from USB requires a USB device to be connected. Backup/Restore to/from network requires an established connection to a network with file sharing capabilities. Restoring the Sample Database requires a previous backup to exist.

Backing Up the Sample Database

This feature allows a user to back up the Sample Database to a USB device or network location.

1. From the Sample Database, choose **Backup/Restore**.
2. Select the button associated with the desired action/location (**Backup to USB**, or **Backup to Network**) in order to back up the existing sample database.
3. Once selected, the system will create and save the file to your target destination. A message will display to confirm the backup file was saved successfully. Select **OK** to acknowledge and return to the Sample Database.

Backing Up the Sample Database

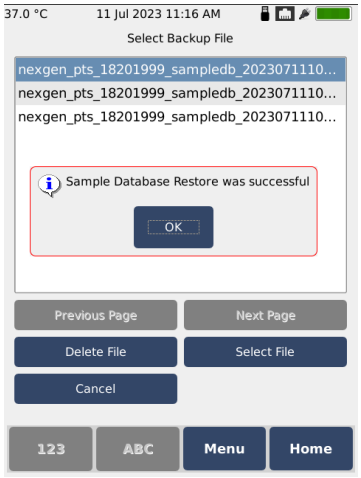
Restoring the Sample Database

This section outlines how to restore a previously backed up sample database. **Restore from USB** will allow a user to restore a previously backed up sample database from a USB device. A previous backup must be located on the USB device. **Restore from Network** allows a user to restore a previously backed up sample database from a network location. If restoring from a USB device or a network location, the instrument must be connected to the desired media.

1. From the Sample Database, select the **Backup/Restore** icon.

2. Select the button associated with the desired action/location (**Restore from USB** or **Restore from Network**) in order to restore the sample database from a previous backup.
3. When **Restore** is selected, a list of previous backups will be displayed. **(Note: The file extension is in the YYYYMMDDHHSS format [Year, Month, Day, Hour, Second]. This is beneficial in locating the correct backup file.)**
4. Select your desired backup file from the list and press **Select File**. A dialog will appear indicating that the restore was successful. Press **OK** to return to the **Sample Database.**

Restoring the Sample Database



8.2 Accessory Database

This section describes the process for editing, reviewing, and adding information to the Accessory Database. To access the accessory database, select the **Accessory Database** icon from the **Menu** screen. The accessory database can store any accessories that would be used with a cartridge assay, such as pipettor or LAL reagent water. The accessories utilized from the database can be printed on the report or included as part of an export for traceability.

The Endosafe® nexgen-PTS™ instrument stores an accessory database consisting of Accessory Type, Lot Number, Expiration Date, Description, and Use By Default options. If User Management is **On**, access to certain accessory database functions will be limited to user accounts with appropriate permissions, such as creating, editing, and deleting accessories. All users can view the accessory database and select accessory information with which to load a test.

Note: A maximum of six accessories can be added to a report. If using the Custom Fields option in General Settings, this number may be fewer. The limit to the number of lines for accessories and custom fields is 18.

8.2.1 *Creating a New Accessory*

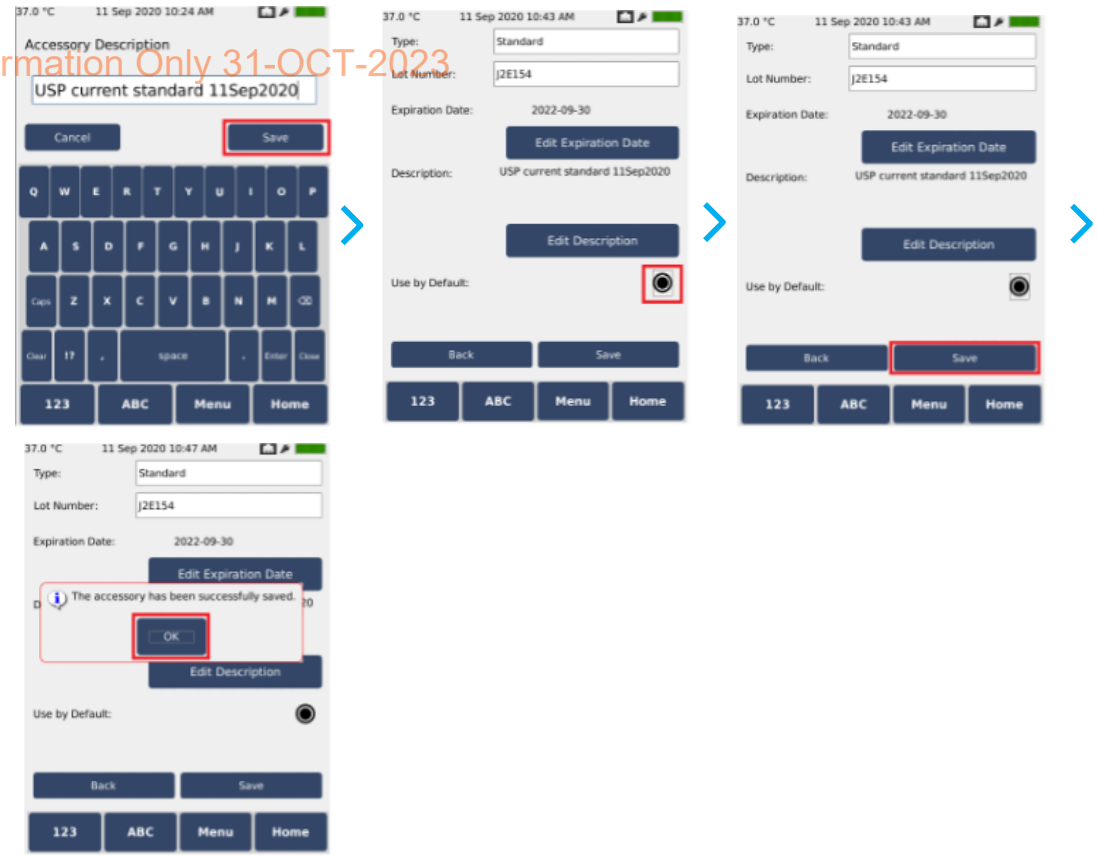
If User Management is **On** (see section 8.5.6), only an Administrator or Manager account can create a new accessory in the accessory database.

1. Select the **Create New Accessory** button.
2. Enter information for the **Type** (character limit is 80).
3. Enter information for the **Lot Number** (character limit is 80)**.**
4. Enter the **Expiration Date**, if necessary, (default setting is 364 days) by selecting the **Edit Expiration Date**. Enter date as YYYY-MM-DD (YYYY = numerical year, MM = numerical month, DD = numerical day) or use arrow buttons to modify the date. Select the **Save** button when complete**.**
5. Enter the **Accessory Description**, if necessary, by selecting the **Edit Description** (character limit is 80). Enter the description and select the **Save** button when complete. A prompt will display, “The accessory has been successfully saved”. Press **OK.**

	Description will not display on report but is available for Charles River Cortex™ application.

6. Select **Use by Default**, if desired. This option allows the accessory to be added to the report as a default accessory, which allows the analyst to save time when setting up an assay. Accessories can be selected during the assay setup process.
7. Select the **Save** button when finished. A prompt will display, “The accessory has been successfully saved”. Press **OK**.

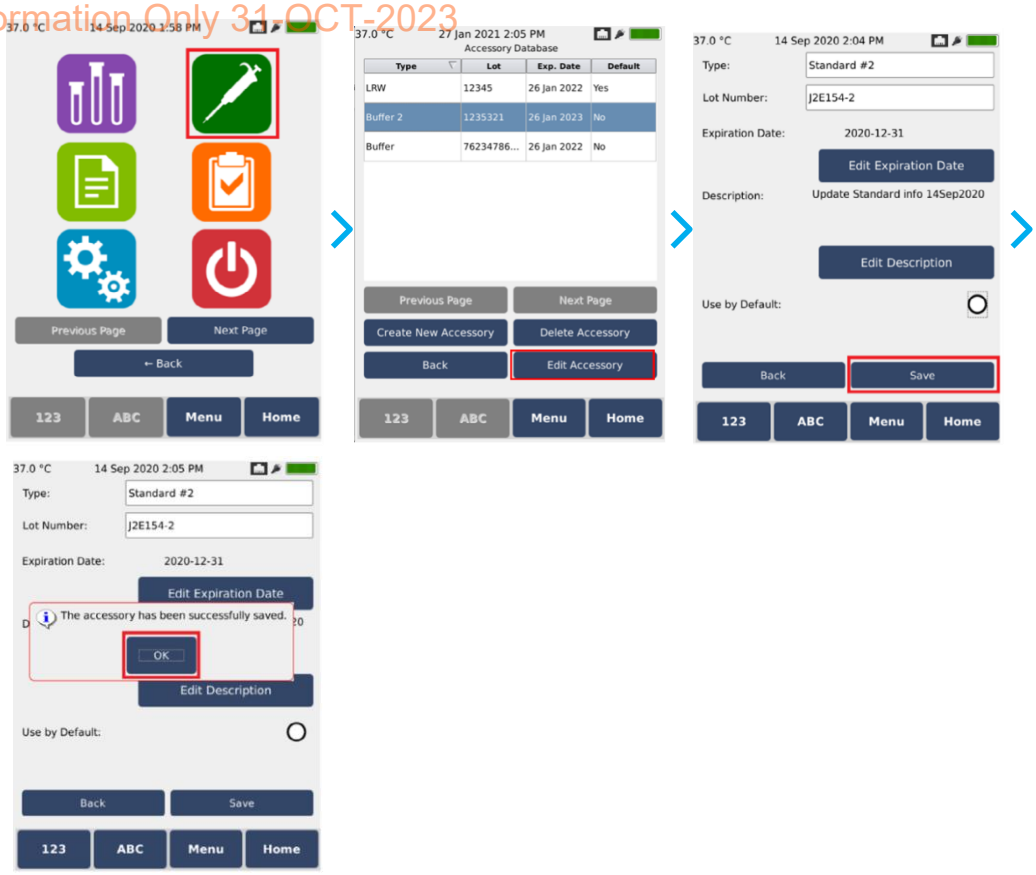
Accessory Database



8.2.2 *Editing an Accessory*

If User Management is **On**, only a user with appropriate permissions can edit the accessory database. This section describes how to modify an existing accessory.

1. Select the accessory database row to edit.
    a. The **Previous Page** and **Next Page** buttons can be used to navigate through the accessory database on the instrument.
2. Select the **Edit Accessory** button.
3. Select the field that needs to be edited (Type, Lot Number, Expiration Date, Description, or Use By Default). See section 8.2.1 for details on each field**.**
4. Select the **Save** button when complete. A prompt will display, “The accessory has been successfully saved”. Press **OK.**



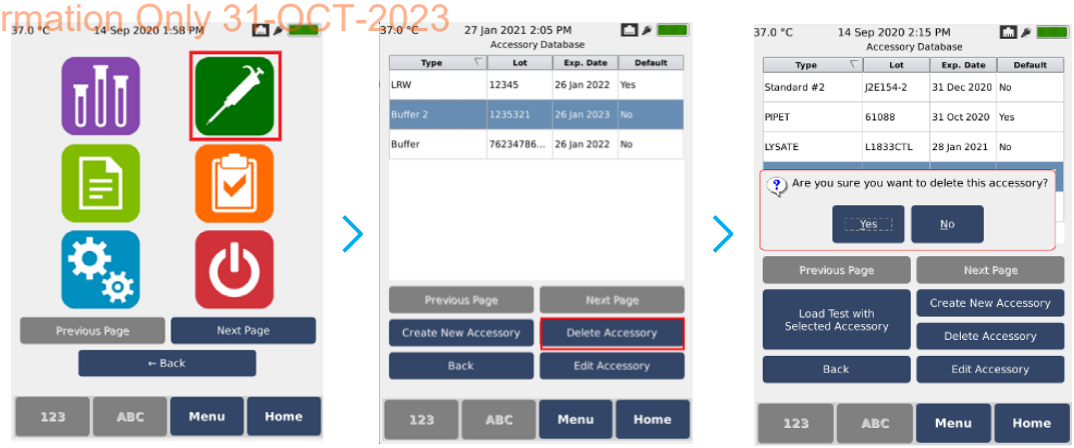
8.2.3 *Deleting an Accessory from Database*

If User Management is **On**, only a user with appropriate permissions can delete an accessory by type in the accessory database. This section outlines how to delete an accessory from the database. Once an accessory is deleted, it cannot be restored.

1. Select the accessory database row to delete.
    a. The **Previous Page** and **Next Page** buttons can be used to navigate through the accessory database on the instrument.
2. Select the **Delete Accessory** button.
3. A prompt will display, *"Are you sure you want to delete this accessory?"* Press **Yes** to delete the row or **No** to cancel**.**

Note: Deleted accessories cannot be recovered.

Deleting an Accessory



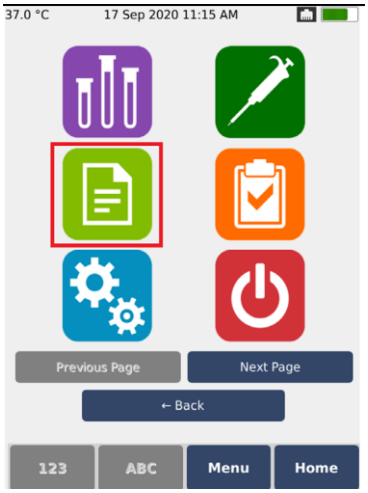
8.3 Results

This section describes the process for accessing, searching, and reviewing test results.

To access test results, select the **Results** icon from the **Menu** screen. The Endosafe® nexgen-PTS™ instrument has space to store thousands of results, however if the number of stored results gets too big, there is the ability to clear results to ensure accessing prior reports does not take more time than necessary. The instrument displays all test results that have not been cleared. If User Management is **On**, only a user with the appropriate permissions can clear and restore reports.

For **restoring test reports** that have been cleared, see section 8.5.5.5.

Results



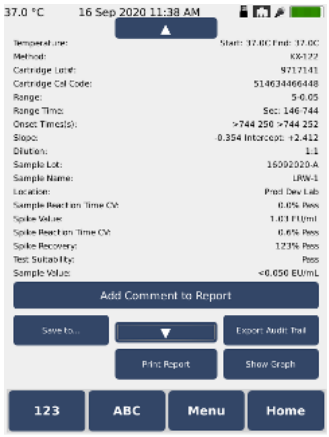
8.3.1 *About Results*

All completed assay results are stored on the instrument and will be accessible from the **Results** screen. For tests that are halted or aborted, a test report will be available under the Results icon if this setting is enabled.

1. Test Suitability
    a. At the completion of a test, the results for that test will display. If the results are invalid or do not pass the defined limits, the invalid section(s) of the test will be highlighted in red. Test suitability will fail if the Sample CV%, Spike CV%, and/or Spike Recovery is invalid or if the endotoxin limit is exceeded.

Test Reports – Test Suitability

"Invalid/Did not pass" test report



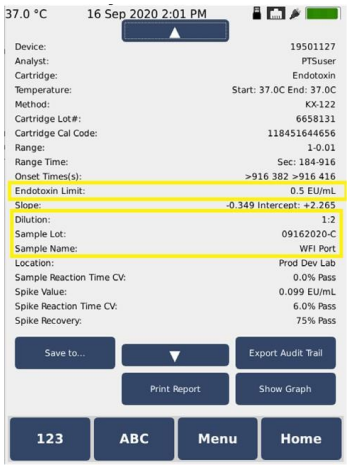
"Passed" test report

2. Sample Information
    a. Manually entered the above displayed sample information can be entered manually during assay setup. The character limit for sample name is 120 characters.
    b. Sample information displayed can be loaded from the sample database table during assay setup or pre-loaded (see Section 8.1).

Sample information reported includes *Sample Name, Sample Lot, Dilution, and Endotoxin Limit*.

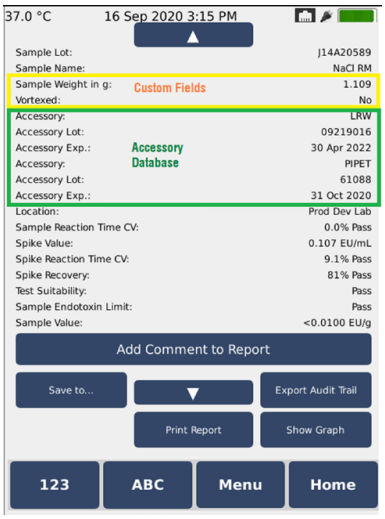
Note: ***Endotoxin Limit will not appear if the General Settings feature for Endotoxin Limit is turned OFF or if the Endotoxin Limit is intentionally left blank***.

Test Results – Sample Information



3. Accessory Database/Custom Fields (Limit 18 lines)
    a. The accessory database displays accessory information for accessories used in conjunction with the assay.
    b. Custom Fields are additional field(s) displayed if added in General Settings (see Section 8.5.5). If User Management is **On**, only an Administrator or Manager account can setup this feature.

Test Results – Accessory Database/Custom Fields



4. Add Comments to Test Report

If User Management is **On**, only an Administrator or Manager account can enable adding comments to the test report. This feature will be displayed if Post-Assay Comments is **On** in General Settings (see Section 8.5.5). The maximum amount of characters to make comments is **30**. A user can add up to **10** post-assay comments to one assay.

    a. A comment can be added after an assay is complete or in the results view table by selecting **Add Comment to Report**. Type your comment and select **Save**.
    b. A comment can be cleared by selecting **Clear All Comments**. A prompt will display, *"Comments have been cleared from this test report"*. Press **OK.**

Test Reports – Add Comments to Test Report

8.3.2 *View and Print Test Reports and Graphs, Save Test Results, and Export Audit Trail*

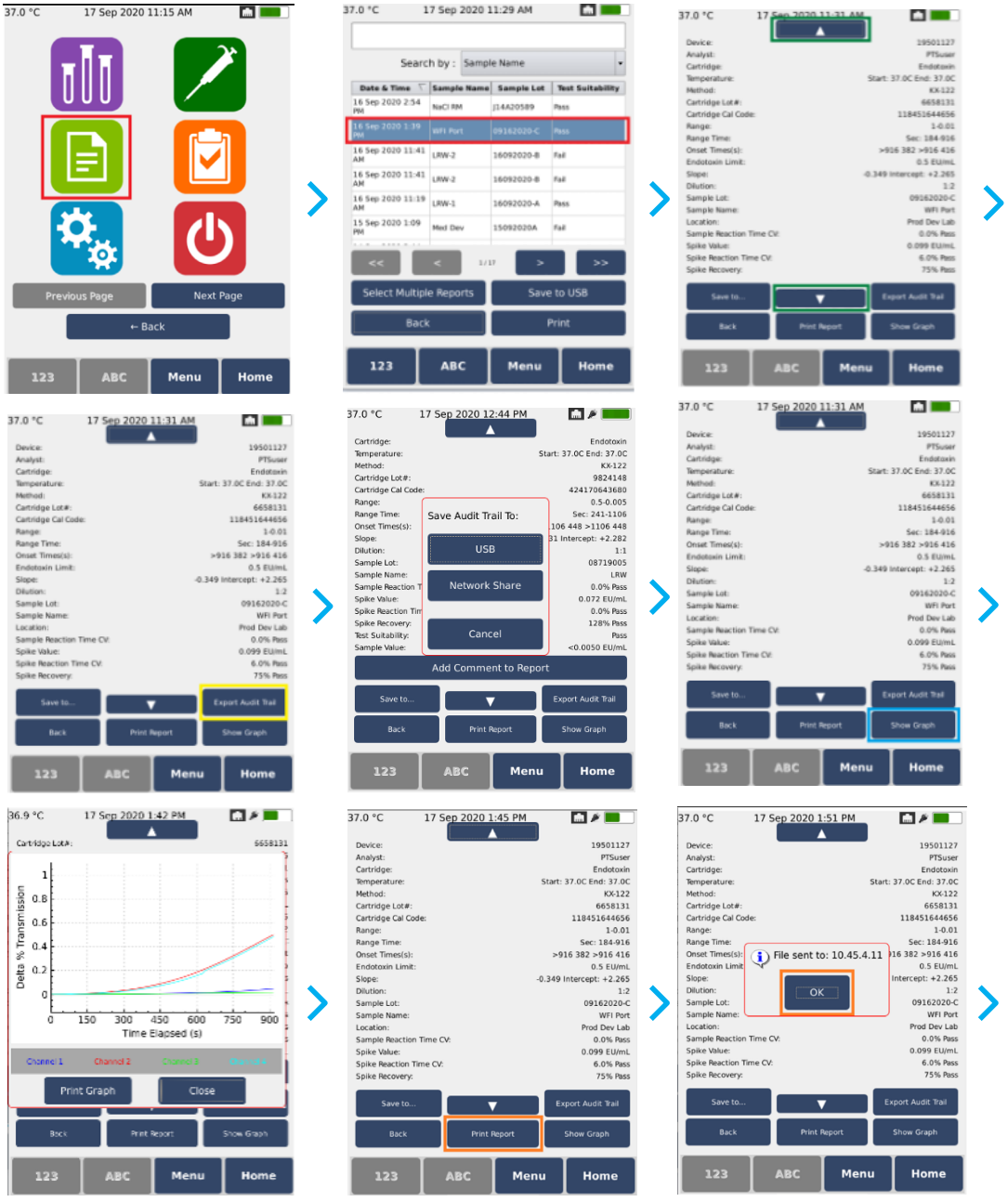
All user accounts can view and print test reports. The test reports contain validity information for the assay(s) run.

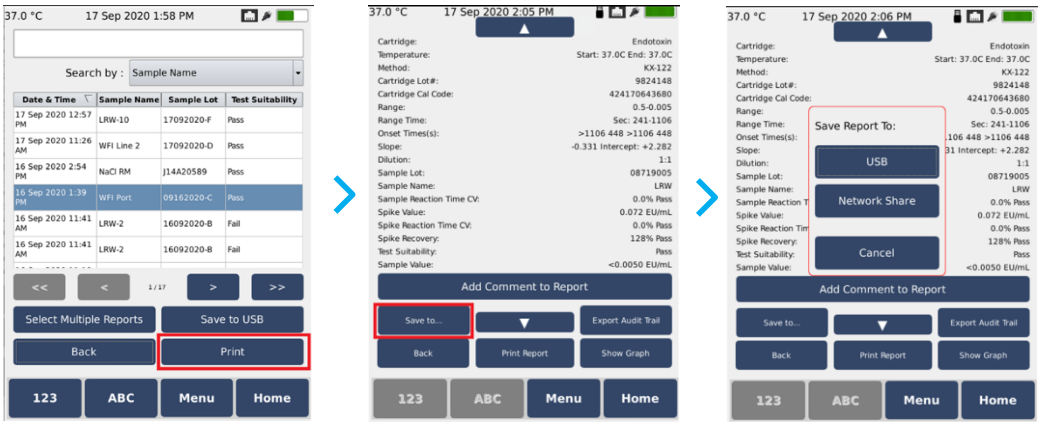
Note: The default view of a report shows the bottom of the report first, as this shows the validity criteria for an assay. It may be necessary to use the *Up and Down arrows* to view the whole report.

1. Select a test result to view on the screen.
    a. The **Previous Page** and **Next Page** buttons can be used to navigate through all reports on the instrument.
2. The report will display the complete results of that assay. The results initially shown will be the bottom of the report, detailing the sample results and validity criteria. To view the analyst and cartridge Information, use the **Up Arrow**.
3. The complete report can be reviewed by using the **Up Arrow** and **Down Arrow** buttons at the top and bottom of the screen.
4. The user can export the audit trail by selecting **Export Audit Trail**. The audit trail can be saved to a connected **USB** device or **Network Share** drive. A prompt will display, *"The Audit Trail has been saved to the USB device or Network Share."*
5. If the **Graph** feature is turned on, the user can elect to show the graph using the **Show Graph** button. The user has the option to **Print Graph** or **Close**. If the user selects **Print Graph**, the graph will be sent to the default printer.
6. The user can elect to print the report using the **Select Multiple Reports** or **Print** button to a configured printer. If the setting requiring a password to print the report has been turned on by the Administrator, the user will have to enter their password before printing. Double-clicking on an assay in the database will open the report of that assay. By using **Select Multiple Reports**, the user can highlight multiple assays and print them at the same time.
   Note: Only one assay can be viewed on the instrument's interface at one time.
    a. The **Print** button allows you to print a single selected report after it was viewed or print multiple selected reports.
    b. The **Select Multiple Reports** button allows the user to select multiple reports to print by dragging their finger over each desired assay.
    c. The **Clear Selection** button clears the selected reports.
    d. The **Print Report** button is only available on the single report view, and it allows a viewed report to be printed. A prompt will display *"File sent to: (Printers Name)"*. Press **OK**.

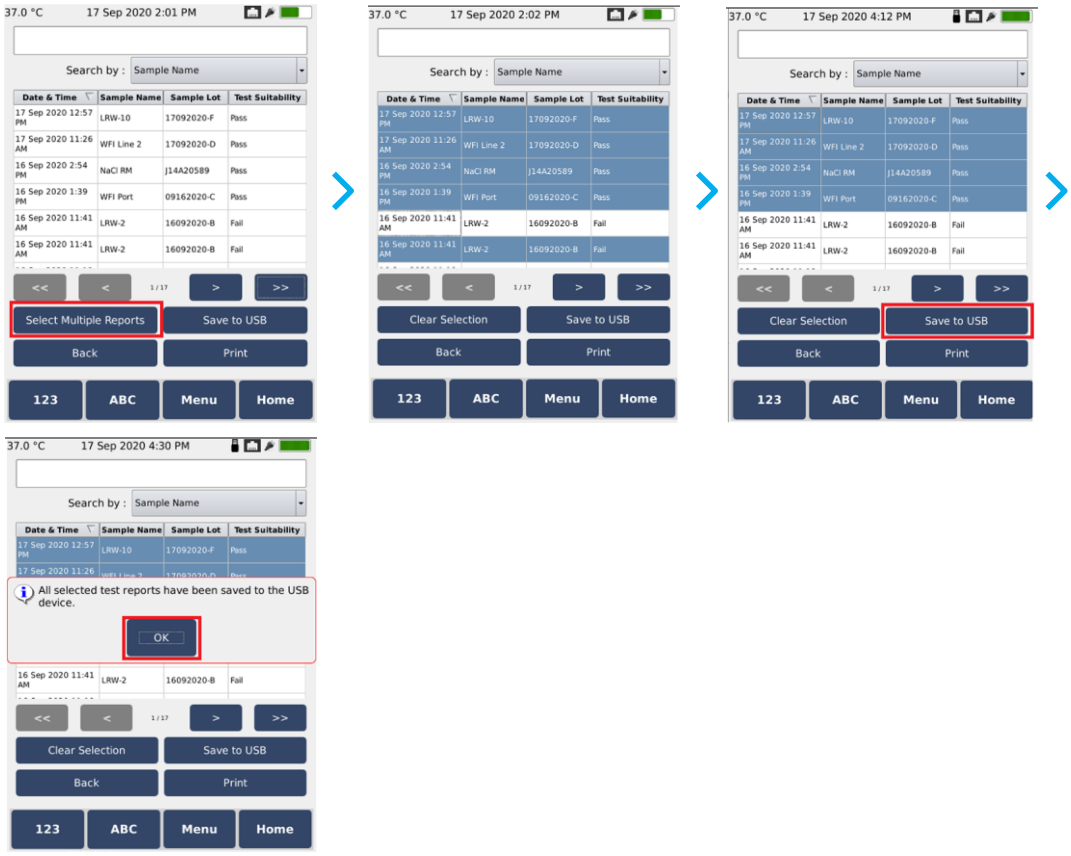
7. The user can elect to save the report using the **Save to USB** or **Save to**. . . button, depending on what screen the user is viewing. If the user is viewing all reports, they can select **Save to USB** in order to save the selected report(s) to a USB device. If the user is viewing a single report, they can select the **Save to**. . . button to save to a USB device or configured network share folder.
    a. The **Save to USB** button allows the user to select single or multiple reports to save to a USB device. A prompt will display *"All selected test reports have been saved to the USB device."* Press **OK**.
    b. The user also can use the **Save to**… button to save a PDF copy of the test report to a connected USB or network share folder. Once an option is selected, a prompt will display *"The report has been saved to the USB device." or "The report has been saved to the Network Share."* Press **OK**.

View and Print Test Reports





View and Print Test Reports

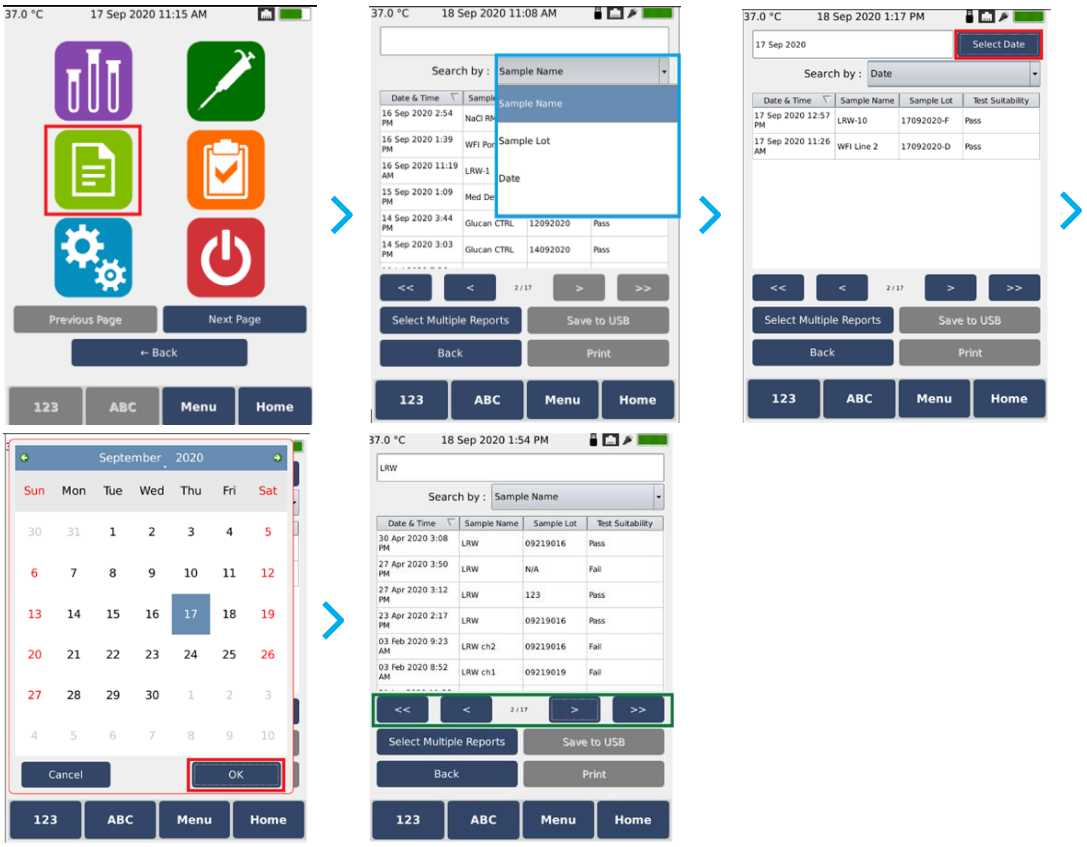


8.3.3 *Search for Test Reports*

All user accounts can search for test reports. This feature allows a user to search by a keyword for the *Sample Name, Sample Lot, or Date*.

1. Use the drop-down menu near the **Search** field to select search criteria, such as Sample Name, Sample Lot, or Date.
    a. Input the search criteria in the open field at the top of the screen for **Sample Name** or **Sample Lot**.
    b. When a date is selected, the user can type DD-MMM-YYYY or press the **Select Date** button. A calendar pop-up will allow you to select the date. Once you've chosen the date, press **OK**.
2. As the search criteria is typed, the instrument will update, showing only test reports that fit the criteria.
    a. **The Previous Page (< or <<) and Next Page (> or >>)** buttons can be used to navigate through all search results. The less than sign (<) will take you back one page while two less than signs (<<) will take you to the first page of results. The greater than sign (>) will take you forward one page while two greater than signs (>>) will take you to the last page of results.

Search for Test Reports



8.4 Audit Trail

The audit trail contained within the Endosafe® nexgen-PTS™ instrument tracks every change made to the instrument settings, as well as attempted logins, successful logins, and the beginning and end of every test. If a setting was changed, it will show the old value for that setting, such as *User Management Off*, and the new value for that setting, such as *User Management On*. This does not apply to passwords.

All user accounts can access the audit trail and view its contents. To access it, press the **Audit Trail** icon on the **Administration** screen. To print or store audit trail entries, save the log files to a USB Device (see section 8.7.2). Additionally, under the **Report** section, there is an option to *Export the Audit Trail* (see section 8.3.2).

Audit trail entries are defaulted to be listed in order by time stamp. One can also sort by *User* and *Action* by selecting the appropriate column header. If *User Management* is turned **On**, the audit trail also records the user associated with that entry.

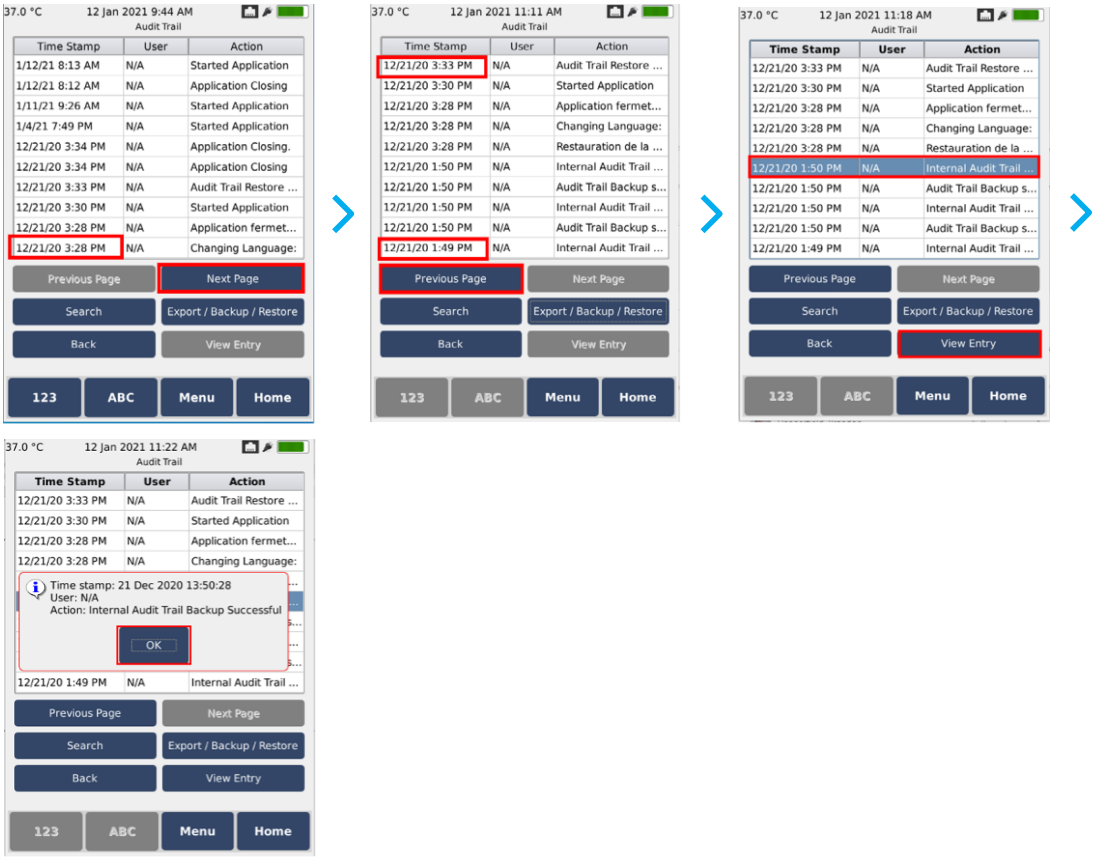
Accessing the Audit Trail

8.4.1 *Navigating the Audit Trail*

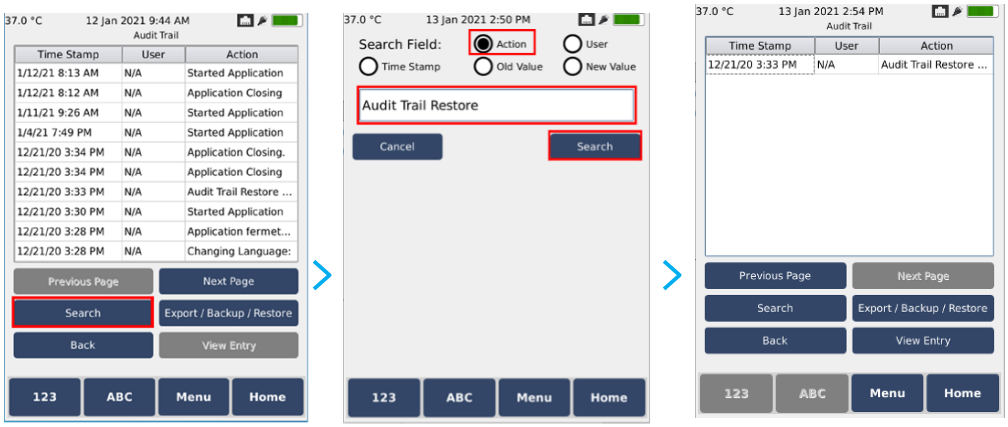
This section outlines how to navigate through the audit trail and view audit entries.

1. Press the Next Page button to navigate to the next page of audit entries. The Previous Page button can be used to navigate to the previous page of audit entries.
2. Alternatively, users can search the audit trail for entries by Action, User, Time Stamp, Old Value, or New Value by pressing the Search button. From this menu, select the desired Search Field, enter the desired value, and press the Search button. A list of entries filtered to the user's specifications will be displayed.
3. Select an entry and press the View Entry button to view additional details.
4. When the user is done viewing the entry, press the OK button to return to the audit trail.

Navigating the Audit Trail Using Page Buttons and Accessing Entries



Navigating the Audit Trail Using Page Buttons and Accessing Entries



8.4.2 *Backing Up, Restoring, and Exporting*

It is possible to backup, restore, and export the audit trail from the **Audit Trail** menu. From the **Audit Trail** menu, press the **Export/Backup/Restore** button in order to access these functions. A user can back up the audit trail, which can archive the audit trail either on the instrument or externally, if desired. When the audit trail is being backed up, there will be a prompt to either start with a fresh audit trail or to add new entries to the current audit trail. Restoring an audit trail allows a user to restore to a previously backed up one, but note that this action **will** overwrite previous entries. The **Restore** action will be noted in the new audit trail. Exporting the audit trail allows a user to save it to a USB device or a network location as a PDF.

8.4.2.1 Backup/Restore

From the **Export/Backup/Restore** menu, press the **Backup/Restore** button. A menu will appear, allowing the user to backup or restore the audit trail to or from internal storage, a USB device, or a connected network.

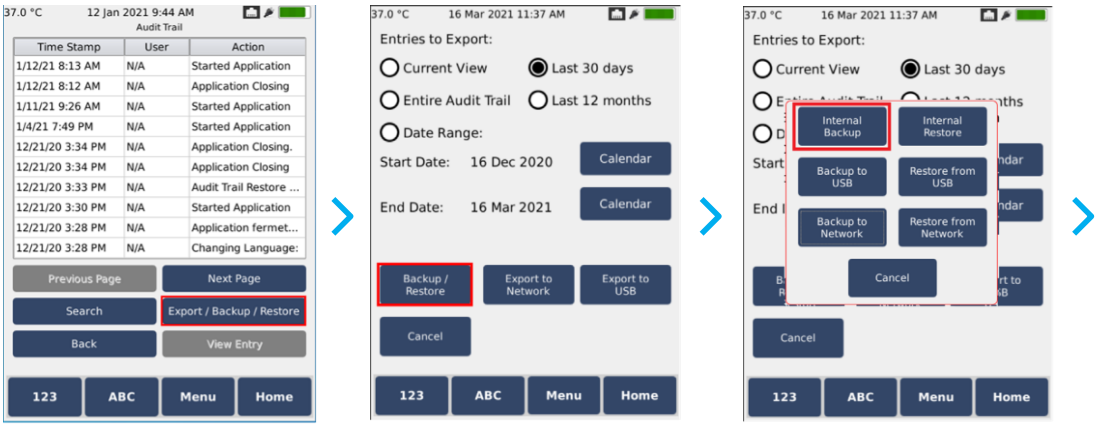
	**Backup/Restore to/from USB requires a USB device to be connected. Backup/Restore to/from network requires an established connection to a network with file sharing capabilities. Restoring the audit trail requires a previous backup to exist.**

Backing Up the Audit Trail

This feature allows a user to back up the audit trail to a USB device or network location or to an internal location. Backing up to an internal location allows users that may not be able to utilize a USB device or network location, but who still wish to have the ability to archive the audit trail and start fresh.

1. Select the button associated with the desired action/location (**Internal Backup, Backup to USB, or Backup to Network**) in order to back up the existing audit trail.
2. When backing up the audit trail, it can be archived from the instrument. A dialog will appear asking *"Do you want to start with a fresh audit trail?"* If **Yes** is selected, after the backup is complete, the new audit trail will have the archive entry only. If **No** is selected, after the backup is complete, it will have the prior entries as well as the archive entry. Also, after the backup is complete, a follow-up dialog will appear, indicating that the archive was successful. The archived audit trail will be located either in the internal backup of the instrument, a USB device, or a network share, depending on the location chosen. Press **OK** to return to the **Export/Backup/Restore** menu. To navigate back to the audit trail screen, select the **Cancel** button.

Backing Up the Audit Trail



Restoring the Audit Trail

This section outlines how to restore a previously backed up audit trail. **Internal Restore** will allow the instrument to restore the audit trail from a previous backup stored on the instrument on the internal memory. **Restore from USB** will allow a user to restore a previously backed up audit trail from a USB device. A previous backup must be located on the USB device. **Restore from Network** allows a user to restore a previously backed up audit trail from a network location. If restoring from a USB device or a network location, the instrument must be connected to the desired media.

1. Select the **Backup/Restore** icon.
2. Select the button associated with the desired action/location (**Internal Restore, Restore from USB, or Restore from Network**) in order to restore the audit trail from a previous backup.
3. When **Restore** is selected, a list of previous backups will be displayed. (**Note: The file extension is in the YYYYMMDDHHSS format [Year, Month, Day, Hour, Second]. This is beneficial in locating the correct backup file.**)
4. Select your desired backup file from the list and press **Select File**. A dialog will appear indicating that the restore was successful. Press **OK** to return to the **Export/Backup/Restore** menu.

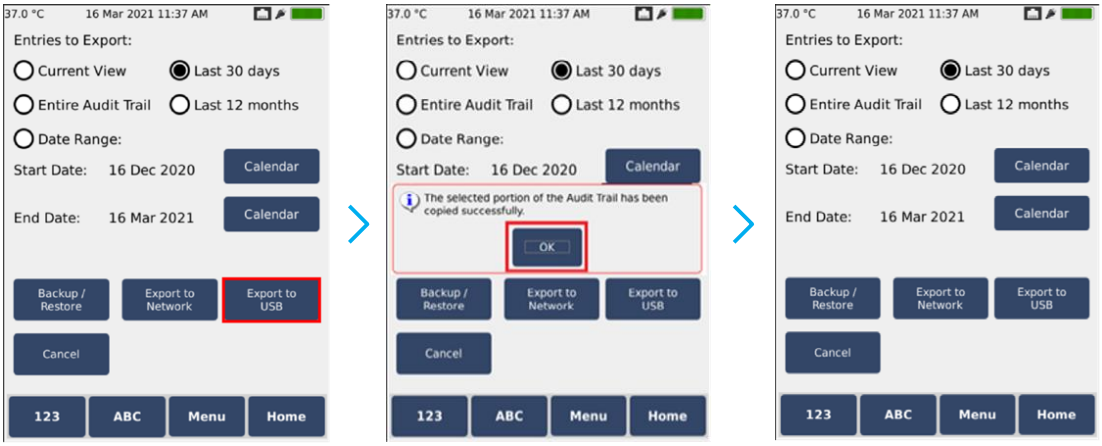
Restoring the Audit Trail

Exporting the Audit Trail (PDF)

Users can export a PDF of the audit trail to a connected network or USB device. An added feature allows the user to filter which entries are shown on the exported PDF.

1. Select **Export to USB** or **Export to Network**. Under the **Audit Trail Entries to Export** screen, select either **Current View, Last 30 Days, Entire Audit Trail, Last 12 Months**, or **Date Range**. **Current View** allows the user to export entries that have been filtered using the Search function within the audit trail menu, **Last 30 Days** will export all entries from the past month, **Entire Audit Trail** will export all entries logged on the device, **Last 12 Months** will export all entries from the past year, and **Date Range** will export all entries within a date range specified by the user.
2. Press the **Export to Network** button to export the chosen audit trail to the connected network drive or **Export to USB** to export to a connected USB device. A buffering ring will appear while the export is taking place.
3. Once the export has completed, a dialog will appear confirming that the audit trail has been successfully copied. Press the **OK** button to exit back to the **Export/Backup/Restore** menu.

Exporting the Audit Trail to a USB Device



8.5 Administration (System Settings)

This section describes configurable options available in the Administration screen. To access the screen, select the **Administration** (system settings) icon from the menu.

If *User Management* is **On**, access to the printer settings and audit trail will be available to all user accounts. Access to the **Languages, Date and Time, General Settings, Networks**, and **Calibrate Touchscreen** screens will be available to user accounts with the appropriate permissions or to an Administrator (see section 8.5.6).

	If *User Management* has been turned **On** (see section 8.5.6), access to certain administration options (system settings) will be limited by user account (the button will be inaccessible and displayed grey) and the permissions granted to that user.

Administration Screen (System Settings)

8.5.1 *Languages*

The Endosafe® nexgen-PTS™ instrument can be configured to be in English, French, German, Italian, Spanish, and Brazilian Portuguese. If *User Management* is **On** (see section 8.5.6), only an Administrator can select the **Language** icon.

1. Select a language from the list of languages available.
2. Press the **Save** button.
3. The Administrator will then be prompted to restart the reader to apply changes in the language selected. Select **Yes** to save and restart, or **No** to cancel changes.

Select a Language

8.5.2 *Network*

This section describes how the Endosafe® nexgen-PTS™ instrument is configured to access a Local Area Network (LAN) using a standard wired Ethernet connection, or a wireless LAN connection using the built-in wireless module. If *User Management* is **On**, only a user with the appropriate permission can select the **Network** icon. To access the **Network Configuration** page, select the **Network** icon from the **Administration** screen. In most cases, the default settings will work. In some cases, where the network is more complex, some advanced configuration settings may be required.

	The wireless module supports only 802.11 b/g.
	When configuring Wi-Fi connection or the Wired Ethernet connection, only one active connection is allowed.
	The SSID and network password are required to set up a wireless LAN connection. The device supports only the WPA-2 security protocol.

	A network that has been set up will become the default network connection. In order to switch from a wired to a wireless network, the Administrator must manually select the method of connection.
	Not all nexgen-PTS ™ instruments are configured with a wireless internet card. Wi-Fi compatibility depends on the region where the nexgen-PTS™ is sold to, as local regulations may not allow for wireless internet.

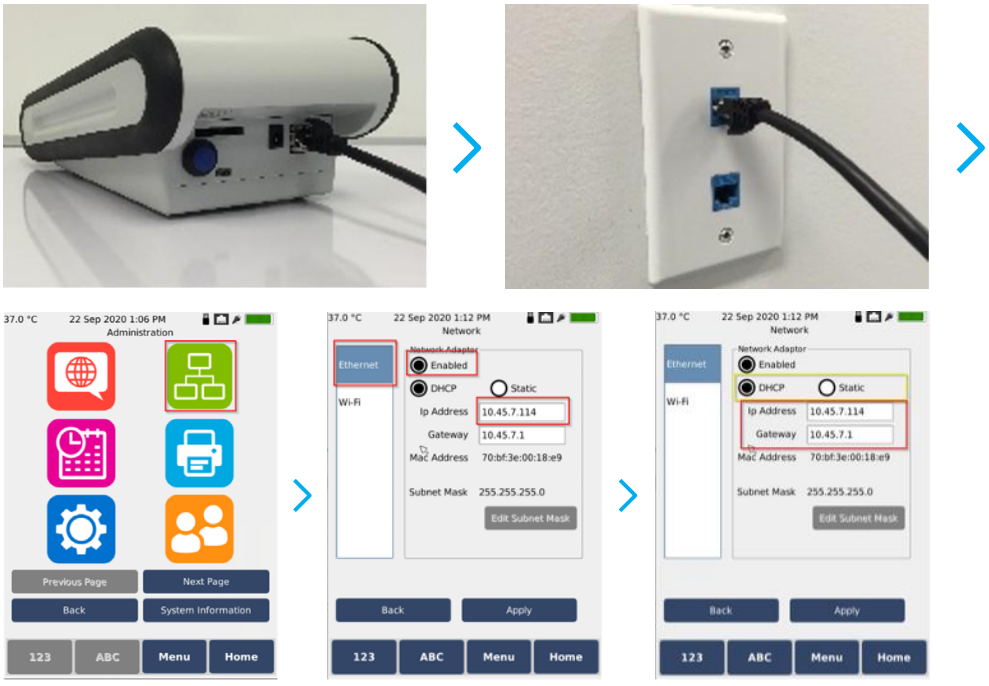
8.5.2.1 Setting Up a Wired Ethernet Connection

1. Insert the supplied Ethernet cable connector into the Ethernet port at the back of the instrument.
2. Insert the other end of the supplied Ethernet cable connector into an available Ethernet port with access to the network.
3. Select the radio button for Enabled.
    a. The radio button will display filled if Wired Ethernet is active.
4. Configure the instrument's wired Ethernet.

- **Static IP Address**: Select the radio button for Static IP Address. The radio button will display filled if Static IP Address has been selected. This option allows the input of a fixed static IP address and Gateway (subnet mask). In this option, the IP and Gateway (subnet mask) will remain fixed until manually changed.
- **DHCP**: Select the radio button for DHCP. The radio button will display filled if DHCP has been selected. When the device is part of a larger network, a DHCP is used. A DHCP IP and Gateway (subnet mask) are automatically assigned by the network server.
- **Mac Address**: Will display on the lower section of the screen.
- **Subnet Mask**: Configurable per network settings at customer.
- **Edit Subnet Mask**: Field to enter a manual subnet mask to work with configured IP address.

5. Select the **Apply** button on the page when complete.

Setting Up a Wired Ethernet Connection



8.5.2.2 Setting Up Wi-Fi (For Models Equipped with a Wireless Module Only)

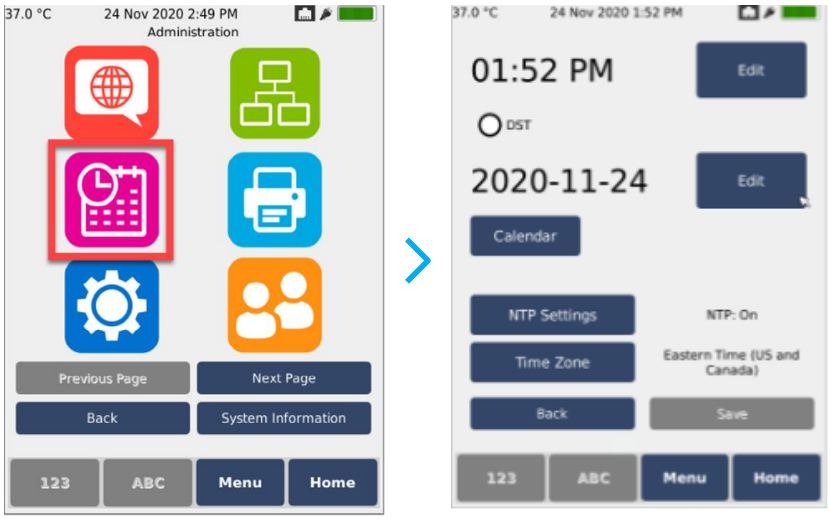
1. Activate the Wi-Fi configuration by selecting the **Wi-Fi** button.
2. Select the radio button for **Enabled**.
    a. The radio button will display filled if Wi-Fi is active.
3. Configure the instrument's Wi-Fi to your network settings.

- **Static IP Address**: Select the radio button for **Static IP Address**. The radio button will display filled if **Static IP Address** has been selected. This option allows the input of a fixed static IP address and Gateway (subnet mask). In this option, the IP and Gateway (subnet mask) will remain fixed until manually changed.
- **DHCP**: Select the radio button for **DHCP**. The radio button will display filled if **DHCP** has been selected. When the device is part of a larger network, a DHCP is used. A DHCP IP and Gateway (subnet mask) are automatically assigned by the network server.
- **Mac Address**: Will display on the lower section of the screen.

4. Select the **Configure** button.
5. Select the wireless network from the list of available wireless networks.
6. Select the **Next Page** button.
7. Select the **security level** (WPA & WPA-2 or None).
8. Select the **Next Page** button.
9. On the **Wi-Fi Settings** page:
    a. Input the SSID for your wireless network in the **SSID** field if you are using a hidden SSID.
    b. Input the password for your wireless network in the **Password field**.
    c. Select the **Accept** button to save the settings before navigating away from the **Wi-Fi Settings** page.
    d. When the **Accept** button is selected, the user will return to the **Network Adapter** page with Wi-Fi already selected.
10. Select the **Apply** button after reviewing the settings summary on screen.

8.5.3 *Date and Time*

This section describes the procedure for setting the **Time Zone, Time**, and **Date**. To access the date and time settings, select the **Date and Time** icon from the **Administration** screen. If User Management is **On**, only a user with appropriate permissions can select the **Date and Time** icon.



8.5.3.1 Setting and Adjusting the Time

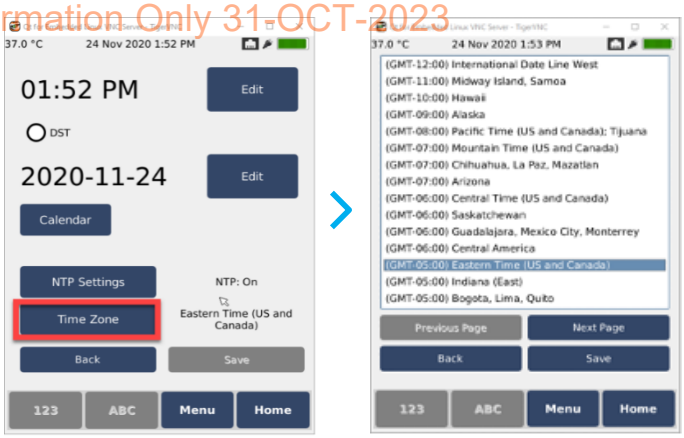
On the **Date and Time** menu, the time is displayed and set in the 24-hour format for all languages except English, which is set to a 12-hour clock. The time will be displayed on test reports and in instrument logs using a 12-hour

format, including AM/PM denotation. The DST button is used to toggle Daylight Savings Time off or on. The currently set time zone is displayed to the right of the Time Zone button. If the displayed time zone is accurate but the system time needs to be adjusted, go to step 4 of this section.

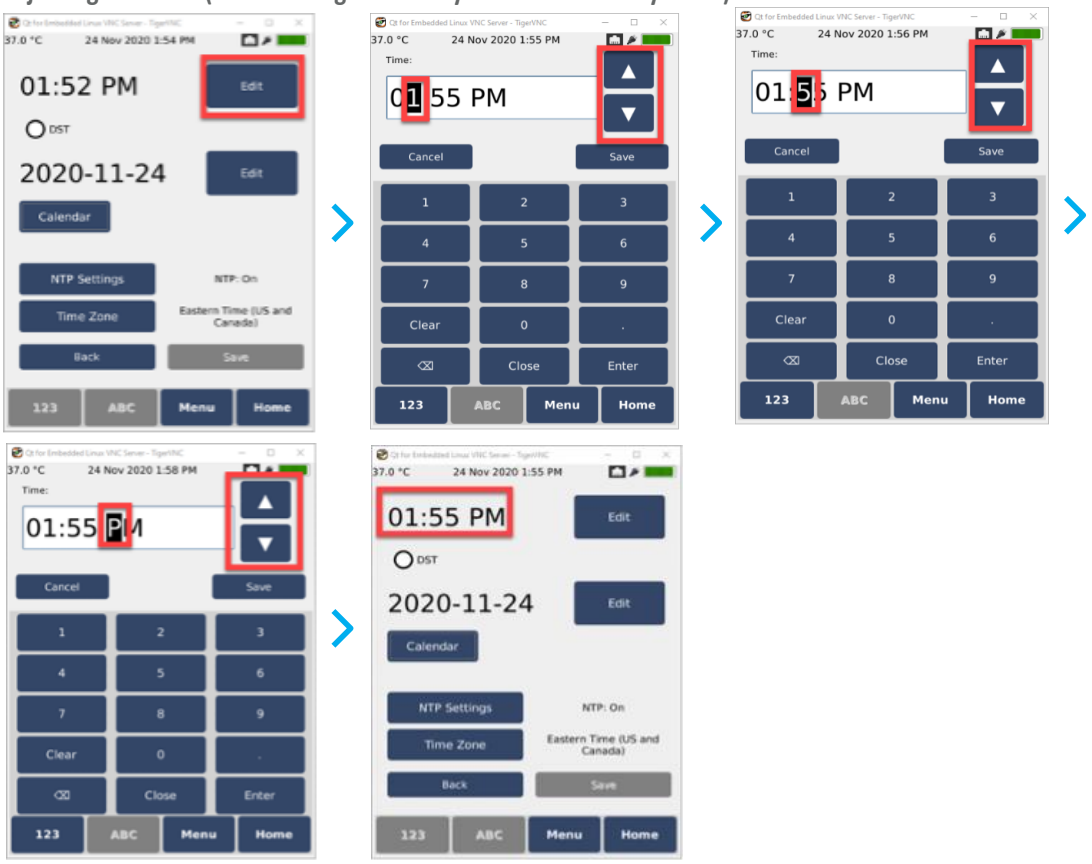
1. Press the **Time Zone** button.
2. Select the local time zone to adjust the instrument's time, offset from GMT (Greenwich Mean Time).
    a. The system will automatically adjust the set time to match the indicated time zone.
3. Press the **Save** button.
4. To adjust the Time:
    a. Press the **Edit** button next to the displayed time.
    b. To change the hour, highlight the rightmost **Hour** digit and use the **Up** and **Down Arrows** to set the correct hour. The numeric keyboard can be used to type the correct digit. Highlight the digit to be changed and enter the desired number on the keyboard.
    c. To change the minute, highlight the rightmost **Minute** digit and use the Up and Down Arrows to set the correct minute. The numeric keyboard can be used to type the correct digit. Highlight the digit to be changed and enter the desired number on the keyboard.
5. When the time is set, press the **Save** button (this button will be accessible if a change has been made).

	**DST** (Daylight Savings Time) can be selected to increment the time forward one hour during the Daylight Savings Time period. This feature changes the time only when selected; it does not automatically update the time for Daylight Savings. This radio button can be selected to adjust to Daylight Savings Time. When Daylight Savings is over, de-select this button.

Setting the Time Zone



Adjusting the Time (Shown using Arrow Keys and Numeric Keyboard)



8.5.3.2 Setting the Date

Adjustment of the date can be accomplished via manual adjustment of the day/month/year digits (similar to setting the time) or by accessing the unit's digital calendar and selecting the desired date. Date is displayed in the YYYY-MM-DD format (YYYY = numerical year, MM = numerical month, DD = numerical day).

Setting the Date Manually:

1. Press the **Edit** button next to the displayed date.
2. To change the day, select the rightmost **Day** digit and use the **Up** and **Down Arrows** to cycle through the days.

3. To change the month, select the rightmost **Month** digit and use the **Up** and **Down Arrows** to cycle through the months.
4. To change the year, select the rightmost **Year** digit and use the **Up** and **Down Arrows** to cycle through the years.

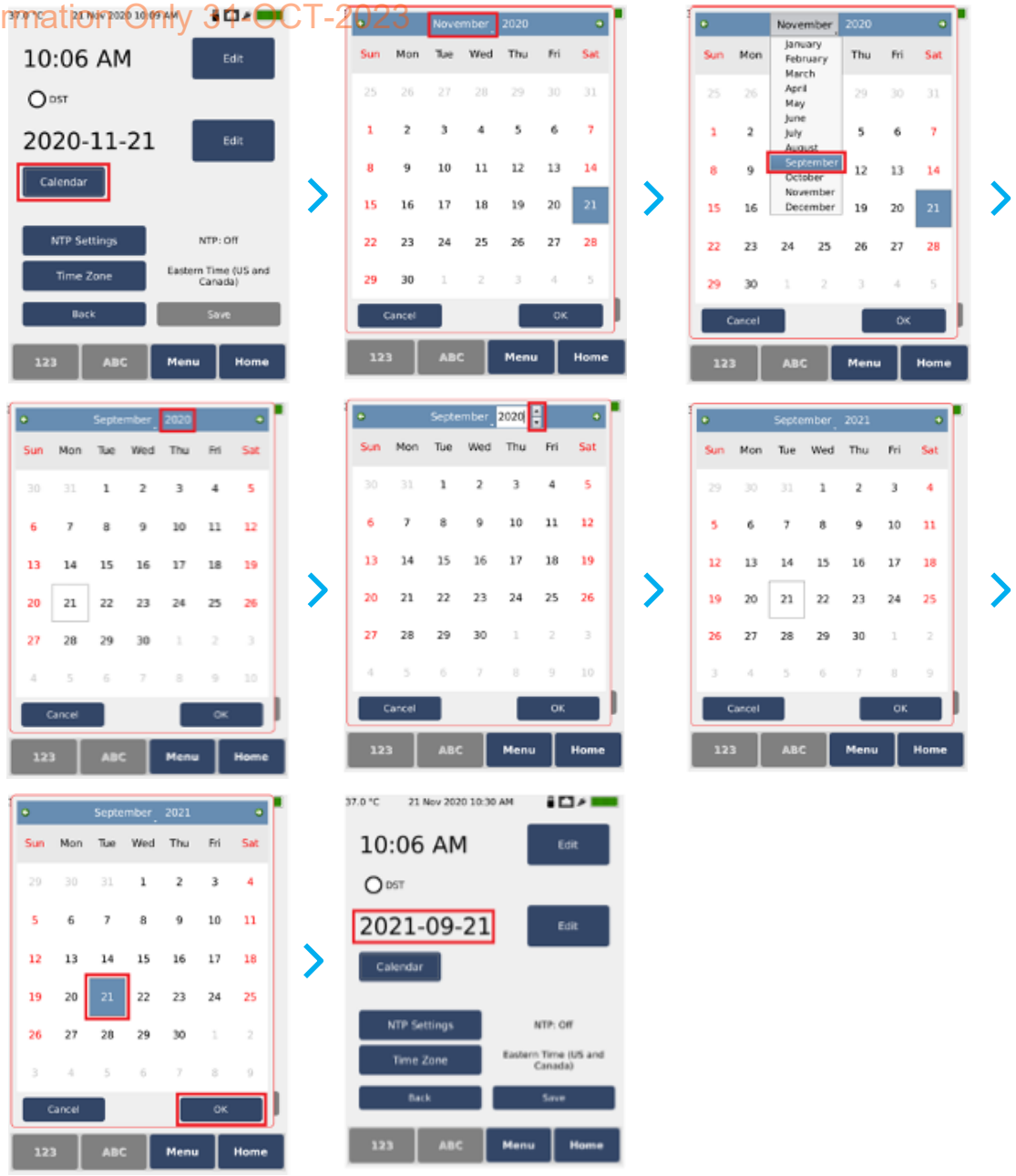
Setting the Date via the Calendar:

1. Press the **Calendar** button below the displayed date.
2. Press the **Month** at the top of the screen to display a drop-down menu containing the months of the year. Select the correct month in the drop- down menu to set it. **(Note: The arrows located at the top left and right corners of the screen may be used to scroll through the months in succession.)**
3. Press the **Year** at the top of the screen to display a set of arrows. Use these to set the correct year.
4. Once the desired month and year are set, the days of the month displayed will be automatically adjusted to the correct orientation.
5. Select the correct day within the calendar and press the **OK** button to confirm the selected date- or press the Cancel button to disregard changes.

Once the date has been set (manually or via the calendar), press the **Save** button (this button will be accessible if a change has been made).

Adjusting the Time (Shown using Arrow Keys and Numeric Keyboard)

Setting the Date via Calendar



8.5.3.3 NTP (Network Time Protocol)

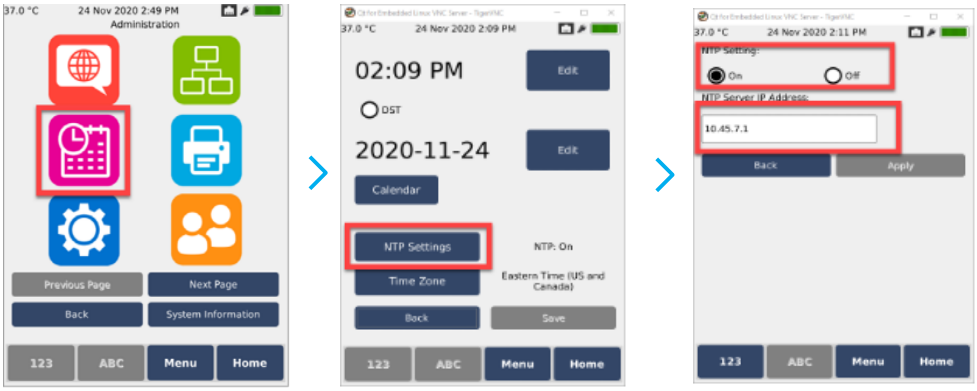
The displayed time on the instrument can update and set automatically when using a valid NTP server IP address. When this feature is enabled, the time on the instrument will sync with that of the selected NTP server if the instrument is connected to a networked system that can reach this server.

1. Select the **NTP Settings** button.
2. The NTP Settings window will display.
    a. To enable NTP, select the **On** radio button.
    b. To disable NTP, select the **Off** radio button.
3. Type in the NTP server IP address.

4. Select **Apply**.

    a. If a connection cannot be established, an error message will display indicating, “There was an error connecting to the NTP server. Please verify the IP address is correct.”
5. When NTP is on and connected to a valid NTP server, the **Date and Time** screen will display NTP: On.
6. The instrument date and time will update approximately 60 seconds after being configured.

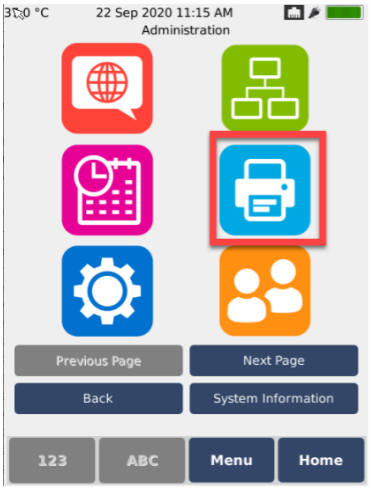
Using NTP



8.5.4 *Printer Configuration*

This section describes how the Endosafe® nexgen-PTS™ instrument is configured to print with a compatible network printer or compatible USB- connected printer (printers must be PostScript compatible). All user types can select the Printer icon and set up printers. Alternatively, a receipt-type printer can be used. Contact your local representative for more information.

To access the **Printer Configuration** screen, select the **Printer** icon from the **Administration** screen.



To print test results, a network or USB printer must be configured as the default printer.

8.5.4.1 Setting Up a Printer

There are multiple ways to print using this instrument:

- **A USB PostScript Printer**: Connect a USB printer to the instrument using the supplied micro-USB (type B) to USB receptacle (type A) cable.
- **A Networked Printer that is PostScript Enabled**: Connect the instrument to a network with compatible printer(s).
- **A Compatible Receipt Printer**: Some models may be able to be networked or connected via USB.

1. Select from the list of available printers to use as the default printer (will display network and USB printers available to the instrument). USB- connected printers will be displayed by the manufacturer's information. Network printers will display manufacturer's information and the IP address.
    a. Select **Refresh Printers** List button if the device is not displayed.
    b. Select **Previous Page** or **Next Page** button to scroll through multiple pages of printers.
2. Select the printer from the list of available printers.

	The instrument will only display network printers on your local network subnet. A nearby printer may be on the same network, but not on your local network subnet. Consult your IT department for more information.

3. Select the Apply button. It will become active when a printer is selected from the list.
4. The name of the current printer will display in the Current Printer field. If the printer is connected successfully, the status will display in the Printer Status field.
5. The set printer will now be the default printer.
6. To test the connection, the user can select Print Test Page. Selecting this button will print a page to the connected printer.

Setting Up a Printer

8.5.4.2 *Adding a Printer by IP Address*

1. Connect the instrument to the network that the printer is connected to via Wi-Fi or Ethernet.
2. Select the **Add by IP Address** button.
3. Enter the printer's IP address. **(Note: Ensure a valid IP address for a printer is added. The instrument cannot detect an invalid printer IP address.)**
4. Select the **Save** button.
5. A window will be shown stating that the printer has been added and asking if you would like to print a test page.
6. Select the **Print Test Page Now** button.
7. Verify that the test page printed properly.

Adding a Printer by IP Address

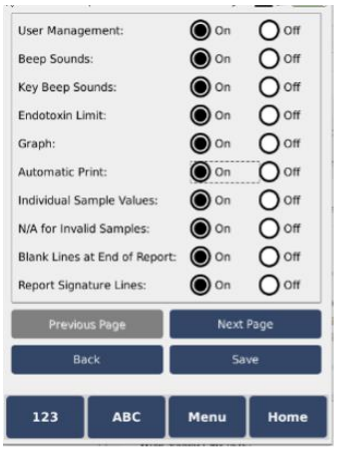
8.5.5 *General Settings*

This section defines the general settings that can be configured on the instrument. To access the general settings, select the **General Settings** icon from the Administration screen. If User Management is **On**, only an Administrator (or user with the Change Setting permission) can select the **General Settings** icon. When modifying the general settings, select the **Save** button to save changes. To scroll through the pages of General Settings, press **Next Page** or **Previous Page**.

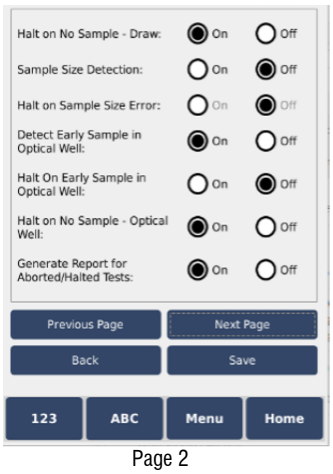
The user will be notified by an on-screen prompt that the changes will not take effect until the system is restarted. The user must restart the system at this point to implement the changes. To restart the instrument, select the **Shutdown** icon from the **Menu** screen, then restart.

General Settings

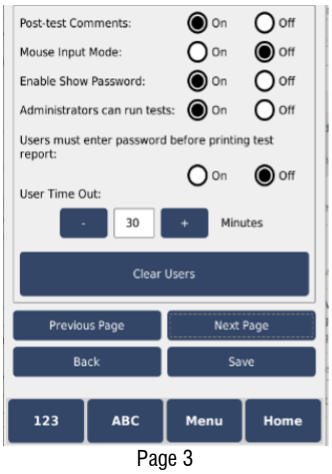
There are five pages of screens:



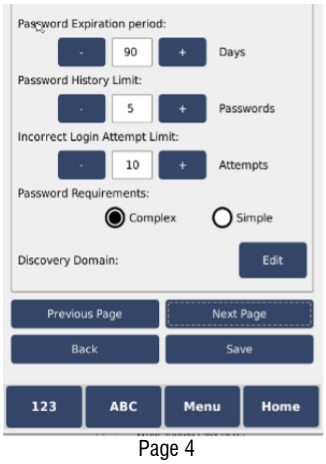
Page 1



Page 2



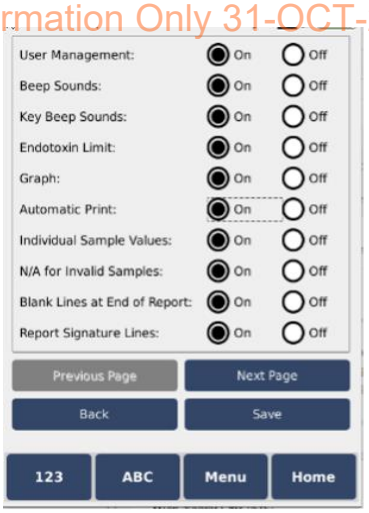
Page 3



Page 4

Page 5

8.5.5.1 General Settings Page 1



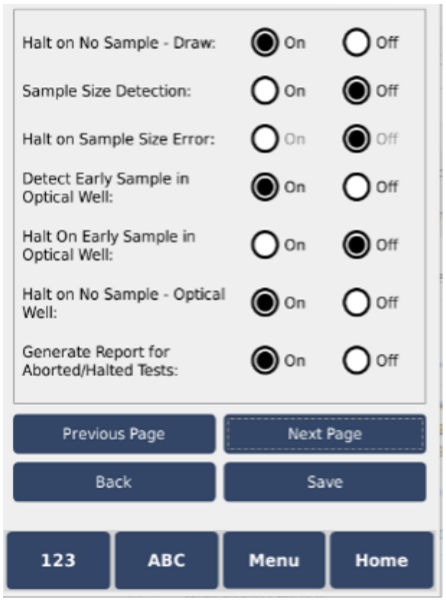
General Settings Page 1 is a selectable page of settings to customize the system. All options are On/Off. When a customized selection is made, select **Save** prior to navigating away from the **General Settings** screens. In order to implement selections, be sure to restart the instrument.

Function	Description/Setting
User Management	**On** – Enables the requirement of user account(s) for access to the instrument. An initial Administrator user type must be created to enable this function (see section 8.5.6).
	Off – Disables the requirement of user account(s) for access to the instrument (see section 8.5.6). If this is disabled, a user can enter an Operator ID for each test if desired.
Beep Sounds	**On** – System will audibly sound during a test.
	Off – System will not make any audible sounds during a test.
Key Beep Sounds	**On** – System will emit a short beep after each key press.
	Off – System will not emit beeps for key presses.
Endotoxin Limit	**On** – Allows the user to enter an endotoxin limit for the test.
	Off – Does not allow the user to enter an endotoxin limit for the test.
Graph	**On** – Displays the absorbance graph during the test.
	Off – Does not display the absorbance graph during the test or when viewing past results.
Automatic Print	**On** – The most recent test report will be automatically printed when a test is finished. A default printer must be set up prior to printing.
	Off – Test reports will not be automatically printed.
Individual Sample Values	**On** – Sample values will be reported individually for each sample well on the test report and as the averaged sample value.
	Off – Sample values will be averaged on the test report.
N/A for Invalid Samples	**On** – Will display “N/A” for Endotoxin Sample Value if the test suitability is “Fail”.
	Off – Will display the Endotoxin Sample Value if the test suitability is “Fail” and an Endotoxin Sample Value exists for that test.
Blank Lines at End of Report	**On** – Blank lines are appended to the end of printed test reports. This feature should only be used with a receipt printer. This will add 30 lines to the report on the receipt paper.
	Off – No blank lines are appended to test reports.
Report Signature Lines	**On** – Will append signature lines to the end of a printed test report for an Analyst and Reviewer.
	Off – Will not append signature lines to printed test reports.

8.5.5.2 General Settings Page 2

General Settings Page 2 is a selectable page of settings to customize the test processing and reports. All options are **On/Off**. When a customized selection is made, select **Save** prior to navigating away from the General Settings screens.

General Settings Page 2



General Settings Page 2

Function	Description/Setting
Halt on No Sample - Draw	**On** – Will halt the test if sample is not detected during the initial pull of the sample. If no sample is detected, the test report will indicate which channel is affected.
	Off – Will show error message if sample is not detected during sample draw and continue the test. The test report will also show the error message.
Sample Size Detection	**On** – The user will receive a notification if too much or too little sample is detected. This is primarily a diagnostic tool to help detect pipetting errors. A precise 25 µl aliquot delivery is required into each well for an accurate assay. The sample size parameters can be adjusted on Page 5 of the General Settings.
	Off – No notification will be made if too much or too little sample is detected. If no sample is detected, then the user is notified that a sample was not detected in one or more wells.
Halt on No Sample Size Error (this setting requires **Sample Size Detection** to be **ON**)	**On** – Will halt the test if "Sample size too large" or "Sample size too small" are detected.
	Off – Will show any applicable error message(s) "Sample size too large" or "Sample size too small" and continue the test, provided Sample Size Detection is enabled. The test report will also show the error message.

Detect Early Sample in Optical Well	**On** – System will monitor optical wells to detect if sample enters the optical well early. This could be an indication that there is an instrument issue or sample volume issue. If this feature is enabled and the test suitability fails, the report will indicate if the sample was detected early in the optical well, provided no other errors occurred.
	Off – Optical wells are not monitored to detect sample entering early.
Halt on Early Sample in Optical Well (this setting requires **Detect Early Sample In Optical Well** to be **ON**)	**On** – Will halt the test if sample is detected in the optical well too early.
	Off – Test will continue. Test report will show error message "Sample entered optical well early", provided Detect Early Sample in Optical Well is enabled.
Halt on No Sample - Optical Well	**On** – Will halt the test if sample is not detected when sample is pulled into the optical well.
	Off – Will show error message if sample is not detected when sample is moved to optical well and continue the test. The test report will also show the error message.
Generate Report for Aborted/Halted Tests	**On** – System will generate an abbreviated test report for aborted or halted tests for all error conditions once the sample has been added. **Note**: An aborted test is defined as a user-aborted test, meaning the user pulled the cartridge or otherwise stopped the test from completion. A halted test means that one of the "Halt on …" features is turned **On** and the system stops the test at the time of detection.
	Off – System will only generate a test report for aborted tests once the test readings have started.

8.5.5.3 General Settings Page 3

General Settings Page 3 is a selectable page of settings to customize the system.

General Settings Page 3

General Settings Page 3

Function	Description/Setting
Post-Assay Comments	**On** – Will allow comments to be added to test report after assay completion. This will allow up to 10 individual comments (maximum 30 characters) to be added to a report.
	Off – Does not allow comments to be added after the test is completed.
Mouse Input Mode	**On** – This feature allows a USB mouse to be plugged into the unit. Enabling this feature will disable the touchscreen on the unit.
	Off – Does not allow the use of a USB mouse.
Enable Show Password	**On** – Will give the user the ability to allow or not allow the display to show password characters when a user is entering their password upon login. **User Management** must be **On** for this feature.
	Off – Will hide password characters when a user is logging in.
Administrators Can Run Tests	**On** – Will allow administrators to run tests.
	Off – Will not allow administrators to run tests.
Users Must Enter Password Before Printing Test Report	**On** – The user is required to enter their password to print test results. In order to use this feature, users must be set up through **User Management**.
	Off – The user is not required to enter their password to print test results.

Setting User Time Out

User Time Out will adjust the amount of time (in minutes) a user can remain inactive before the instrument will log them out (minimum 5 minutes; maximum 999 minutes). To adjust the amount of time in minutes:

1. Select the **Plus (+)** or **Minus (-)** buttons.
2. Select the **Save** button to save the settings before navigating away from **General Settings Page 3** screen.

Clear Users

The **Clear Users** button will remove all users that have been set up in User Accounts. If User Management is **On**, the logged in user will need to enable the permission to clear users. To clear users, select the **Clear Users** button. Dialog box will display, “This will permanently clear all User Accounts. Is this what you want?”:

1. Select **Yes** to remove user accounts or **No** to cancel. Selecting Save is not required.
2. Once the user accounts are cleared, they cannot be recovered.

8.5.5.4 General Settings Page 4

General Settings Page 4 allows for the customization of the password settings.

General Settings Page 4

Setting the Password Expiration Period

Password Expiration Period will adjust the amount of days the user's password will remain valid (minimum 30 days; maximum 999 days). To adjust the amount of days:

1. Select the **Plus (+)** or **Minus (-)** buttons.
2. Select the **Save** button to save the settings before navigating away from **General Settings Page 4** screen.

Setting the Password History Limit

Password History Limit will adjust the number of passwords the instrument will retain and compare to new passwords input by a user. If a user inputs a password that has previously been used within the selected range, the instrument will not allow that password to be used (minimum 1 password; maximum 99 passwords). To adjust the password history limit:

1. Select the **Plus (+)** or **Minus (-)** buttons.
2. Select the **Save** button to save the settings before navigating away from **General Settings Page 4** screen.

Setting the Incorrect Login Attempt Limit

Incorrect Login Attempt Login Limit will adjust the number of incorrect login attempts that the system will allow before deactivating a user. A deactivated user must be re-activated by an administrator (minimum 1 attempt; maximum of 99 attempts). To adjust the amount of incorrect login attempts allowed:

1. Select the **Plus (+)** or **Minus (-)** buttons.
2. Select the **Save** button to save the settings before navigating away from **General Settings Page 4** screen.

Setting Password Requirements

Password Requirements	**Complex** – Passwords must be 8-40 characters and contain at least one uppercase letter, one lowercase letter, and one number or special character.
	Simple – Passwords must contain between 4 and 40 characters of any type.

Setting Discovery Domain

Discovery Domain is a network domain which allows for device discovery which can be used by Charles River Cortex™.

To set the discovery domain select the **Edit** icon and input the connected network domain. The default value for this field is blank:

1. Select the **Edit** icon and input the connected network domain. The default value for this field is blank.
2. Select the **Save** button. The active discovery domain will display in the **Discovery Domain** field.
3. Select the **Save** button to save the settings before navigating away from the **General Settings Page 4** screen.

8.5.5.5 General Settings Page 5

General Settings Page 5 *allows for the customization of the Device Location, Charles River Cortex Server IP, Charles River Cortex Server Port, as well as the ability to enable Automatic Network Save, Change Sample Size Limits, Edit Custom Fields, Clear Lot Numbers and Cal Codes, Clear the Sample Database, Clear Reports, and Restore Reports*.

General Settings Page 5

Setting the Device Location

Device Location is a text description of the device's physical location and is included with the test report. Device location is also utilized through the Charles River Cortex data management software. The maximum number of characters allowed is 18. To change the Device Location:

1. Select the **Edit** button and input the location description.
2. Select the **Save** button.
3. The current device location will display in the **Device Location** field.

Setting the Charles River Cortex™ Server IP

Charles River Cortex™ Server IP is the IP address used to connect to Charles River Cortex™ software. To change the Charles River Cortex Server IP:

1. Select the **Edit** button and input the Cortex™ server's IP address.
2. Select the **Save** button.
3. The current Charles River Cortex™ server IP will display in the **Cortex Server IP** field.

Setting the Charles River Cortex™ Server Port

Charles River Cortex™ Server Port is the TCP port number used to connect to the Cortex product. To change the server port:

1. Select the **Edit** button and input the server's TCP port number.
2. Select the **Save** button.
3. The current Charles River Cortex™ server port will display in the **Charles River Cortex Server Port** field.

Automatic Network Save

The **Automatic Network Save** function allows the instrument to be configured to automatically save reports (.pdf) to a CIFS or NFS share.

	If connecting to a CIFS share, SMBv1 and NTLM must be enabled on the server hosting the share in order to authenticate to a CIFS share. Valid login credentials are required to access the server location. It's recommended that you contact your IT department and verify your network share settings prior to enabling this setting.

To enable this function:

1. Select **ON** for the Automatic Network Save.
2. Click the **Edit** button on the **Share** line and type in your share location. The format will be \\IP address(or Server Name)\Share Name.
3. Once entered, choose the **Connect** option to save it. You may receive an error message, but the setting will save, as not all the settings have been configured yet.
    a. **Note: The format for the Server Name and Share Name must be followed, and do not enter the full folder path here**.
4. Click **Edit** for the **User**: line and enter a user who has access to the Shared folder and click **Save**.

   a. It is recommended to use a Service account or use a user account that is created specifically for the nexgen-PTS™.
   b. This user must have **Read/Write** access to the destination folder and Read and Traverse access for all folders above the destination folder.
5. Click **Edit** for the password and enter the password for the user chosen in the above step, then choose **Save**.
6. Click **Edit** for the Domain and enter the domain for the user account.
   a. If the share location is not connected to a domain or you are using a local user on the share system, use the Computer Name (Hostname) of the share.
7. Once all settings except **Folder** have been set, click the **Save** button at the bottom. A message stating that the share connection was successful should appear.
8. If you would like the data to be saved in a separate folder other than the root of the share, select the **Edit** button on the **Folder** line. Here, you can browse to the folder of your choice.

Changing Sample Size Limits

The Change Sample Size Limits button is used to change the sample size detection limits that are used for different test methods. The minimum sample size is 20 microliters with a maximum sample size of 30 microliters.

	If you are to utilize the Sample Size Detection feature, please ensure that you have fully validated/qualified this feature with each of your sample types.

To change sample size limits:

1. Select the **Change Sample Size** Limits button.
2. Select the appropriate test method (Endotoxin, Beta-glucan [for use with Beta-glucan cartridges only], I/E Screen [for Inhibition/Enhancement cartridges only], or Gram-ID [for Gram-ID cartridges only]) that you want to edit size limits for and select the Edit button.
3. Enter the desired values for the minimum and maximum sample size.
4. Select the Save button.

5. The updated sample size limits will be shown in the list.
6. Select the Back button to return to General Settings Page 5.

Adding, Deleting, or Editing Custom Fields

The Edit Custom Fields button is used to add or delete customized data fields for test reports. Custom fields can be in the form of Text, Number, or a Yes/No button. When enabled and set up, users will be prompted to complete the fields to run an assay. The maximum number of custom fields alone, without the use of accessories from the Accessory Database, is 10.

To **ADD** a new field:

1. Select the **New Field** button.
2. Enter the **Field Name** as it will appear on the test report and when entering test parameters.
    a. Select the **Text** button if the field will have text values.
    b. Select the **Number** button if the field data will have numeric values.
    c. Select the **Yes/No** button if the field data will have yes/no values.
    d. Once complete, select the **Save** button.
3. A prompt will ask if you would like to **Restart Later** or **Restart Now**. The custom field has been saved but will not be used until the system restarts.
4. The system will return to the previous screen and the updated custom field will be shown in the list.

To **DELETE** a custom field:

1. Select the field from the list.
2. Select the **Delete Field** button to delete the field.
3. The custom field will be deleted when the system restarts.

To **EDIT** a custom field:

1. Select the field from the list
2. Select the **Edit** button to edit the field.
3. The custom field will be modified when the system restarts.

Clear Lot Numbers and Calibration (Cal) Codes

The **Clear Lot Numbers and Cal Codes** button, when selected, will remove all cartridge lot numbers and calibration code combinations that have been stored by the instrument.

To clear cartridge lot numbers and calibration codes:

1. Select the Clear Lot Numbers and Cal Codes button.
2. A dialog box will display, *"This will permanently clear all Cartridge Lot Numbers and Calibration Codes. Is this what you want?"*
3. Select **Yes** to confirm or **No** to cancel **(Note: Selecting Save is not required; when Yes is selected, the cartridge Lot Numbers and Calibration Codes are automatically removed).**
4. Once the cartridge lot numbers and calibration codes are cleared, they cannot be recovered.

Clear Sample Database

The Clear Sample Database button, when selected, will remove all stored samples that have been set up in the Sample Database (see section 8.1 for more details). To clear the sample database:

1. Select the **Clear Sample Database** button.
2. A dialog box will display, *"This will permanently clear the Sample Database. Is this what you want?"*
3. Select **Yes** to confirm or **No** to cancel **(Note: Selecting Save is not required; when Yes is selected, the samples are removed).**
4. Once the sample database is cleared, it cannot be recovered.

Clear Reports

The Clear Reports button will remove all stored reports and instrument/ application logs from the instrument. This feature will only clear reports, while the Audit Trail will capture the action. The Audit Trail cannot be cleared – only archived (see section 8.4 for more details). The ability to utilize the Clear Reports button is tied to the Clear Reports permission in User Management. To clear the reports:

1. Select the **Clear Reports** button.
2. A dialog box will display, *"This will clear all logs and all test reports on the PTS. Is this what you want?"*
3. Select **Yes** to confirm or **No** to cancel **(Note: Selecting Save is not required; when Yes is selected, the reports are removed)**. Test Logs are not removed and can be used to restore reports later.
4. Once the reports and logs are cleared, they cannot be recovered.

Restore Reports

The Restore Reports button, when selected, will restore previously deleted reports to the system using their test logs.

	If any comments were made to the report after the assay completed, they will be lost – only the test report will be restored. The ability to utilize the **Restore Reports** button is tied to the Clear Reports permission in **User Management**.

To restore reports:

1. Select the **Restore Reports** button.
2. A dialog box will display, *"This will restore any test reports that have been cleared from this device. Is this what you want?"*
3. Select **Yes** to confirm or **No** to cancel **(Note: Selecting Save is not required; when Yes is selected, the reports and logs are restored)**.

8.5.6 *User Management*

This section describes how to manage user accounts, how to create user accounts, and instrument accessibility by user account type.

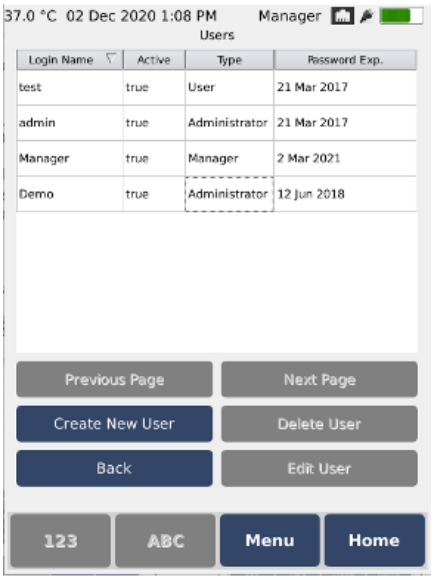
To access user accounts, select the **User Accounts** icon from the **Menu** screen. User accounts can be set up at any point during instrument setup and/or use of the Endosafe® nexgen-PTS™ instrument. The instrument does not come configured with default active users and does not require user accounts to run a test. If *User Management* (requiring log in with a unique username and password, and limiting user access) is required, an initial administrator account must be created.

Once an initial administrator account is added, **User Management** can be turned **On** (see section 8.5.5.1). In order to avoid locking out an administrator account, it is highly recommended that multiple administrator users are created prior to turning User Management On. Additional users can be created before or after the *User*

Management function is turned **On**. If *User Management* is **On** prior to creating an administrator account, access will not be granted to the system.

When *User Management* is **On**, the name of the currently active user account will display in the notification panel at the top of the screen. The default user role permissions can be modified when *User Management* is turned **On**.

User List



- **Login Name**: This column displays the user's login name, as described below. Character length allows up to 40 characters, however it is recommended that a maximum of 20 characters is used.
- **Active**: This column displays whether a user account is active (true) or disabled (false).
- **Type**: The user type describes whether the user is an administrator, manager, or user.
- **Password Exp.**: Displays when the user's password will expire. The default expiration is set to 90 days.

8.5.6.1 Types of User Accounts

There are three types of default user roles, limiting access as noted when User Management is On.

Function	Description
User	Permissions include run tests, view test reports, save test reports to a USB device, print data, and load a test from the sample database. Has access to the **Administration** (system settings) page to set up a printer, view the **Audit Trail** and view **System Information**. This role does not have access to any additional functions, including editing the **Sample Database**, and setting up user accounts.
Manager	Has all the permissions as a User. Additionally, the Manager has full access to the **Sample Database** and **User Accounts** screens.
Administrator	By default, an Administrator has access to the complete instrument. If **Administrators can run tests** is set to **No**, the Administrator cannot run a test.

8.5.6.2 Types of User Accounts

If *User Management* is **On**, only a user with appropriate permissions can create a new user.

1. Select the **Create New User** button.
2. Enter a username in the **Login Name** field. The login name is limited to 40 characters and must have a minimum of three characters.
3. Enter a password in the **Password** field.
    a. If **simple** passwords are being used, the password must be 4-40 characters of any type.
    b. If **complex** passwords are being used, the password must be 8-40 characters and contain at least one uppercase letter, one lowercase letter, and one number or special character.
    c. A message near the bottom of the form serves as a quick reminder of the complexity parameters and changes depending on whether the Password Requirements setting (found in Administration – General Settings Page 4) is configured for **simple** or **complex** passwords.
4. Re-enter the password in the **Confirm Password** field. Select **Show Password** to display the password when typing.
5. Select the **User Type**. If the keyboard is visible, select **Close** to hide the keyboard. This will allow the **User Types** and **Save** buttons to be visible.
6. Select the **Save** button to save the new user. Repeat steps 1-6 for additional new users. They system does not limit the number of users that can be created.

	As users are entering a password, the system will check for display one of the following levels of password strength: Weak (in **red**), Medium (in **orange**), or Strong (in **green**). Passwords are not validated based on strength, only complexity as described above.

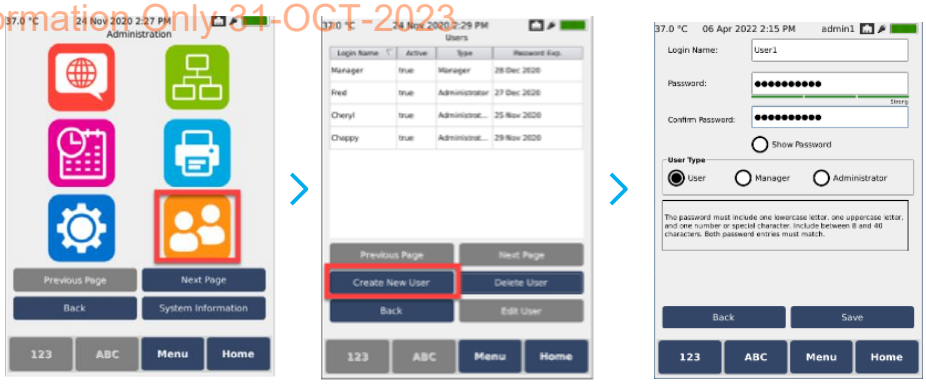
When configuring a user's password, the system will evaluate and display the password's strength in real time.

Password strength is separate from password complexity. Password strength should only be used as a reference when selecting a password; the software does not validate passwords for strength, only complexity (as configured in the Password Requirements system setting).

Password strength is determined by length and number of character types used (uppercase, lowercase, numbers, and special characters):

- **Weak** -- Passwords of any length using one (1) type of character or passwords with five (5) or fewer characters using any combination of character types are marked as weak.
- **Medium** -- Passwords with six (6) or more characters using two (2) to three (3) types of characters are marked as medium strength.
- **Strong** -- Passwords are marked as strong when they are seven (7) or more characters in length and use all four (4) types of characters (uppercase, lowercase, numbers, and special characters).

Create New User



	When *User Management* is **On**, after 30 minutes of inactivity, the user will need to re-enter their password. The last screen viewed will be displayed; select the **Back** or **Menu** buttons to navigate to the **Enter Password** screen. The inactivity time can be set through the *Administration* tab.

8.5.6.3 Change the Currently Active User's Password

All user types can change their own password.

1. Log in using the user's current password.
2. Navigate to the menu by selecting the **Menu** icon.
3. Select the **User Accounts** icon, then navigate to **Login Name → Edit User → Reset Password**.
4. Enter the user's current password in the **Current Password** field.
5. Enter a new user password in the **New Password** field. The password must be 8-16 characters and contain at least one uppercase letter, one lowercase letter, and one number or special character.
6. Re-enter the new password in the **Confirm Password** field.
7. Select the **Save** button to save the new user password.

	Select the Show Password radio button to display the password text.

Change the Currently Active User's Password

8.5.6.4 Reset a Password

If *User Management* is **On**, a user with appropriate permissions can reset a password for another user; a user without permission to modify another user's password can only reset (change) their own password.

	The default password, once changed by an Administrator or Manager, is **pts12345AB**.

An Administrator or Manager can follow these steps to reset an Administrator's, Manager's, or User's password:

1. On the User Accounts screen, select the **Login Name** whose password needs to be reset.
    a. The **Previous Page** and **Next Page** buttons can be used to navigate through all users assigned to the instrument.
2. Select the **Edit User** button.
3. Select the **Reset Password to Default** button.
4. The default password will be changed to **pts12345AB**; select **OK** to confirm.
5. The user will be prompted to enter the default password when logging in and then prompted to create a new password.

Reset a User's Password

8.5.6.5 Delete Users

If User Management is On, only an Administrator or Manager account can delete an Administrator, Manager or User account.

	A Manager only has access to delete login names listed as a Manager or User. Users cannot delete their own user account when logged in. An Administrator can delete all user types.

Delete User

To delete a user:

1. On the **User Accounts** screen, select the **Login Name** to be deleted.
    a. The **Previous Page** and **Next Page** buttons can be used to navigate through all users assigned to the instrument.
2. Select the **Delete User** button.
3. A prompt will display, *"Are you sure you want to delete this user?"* Press **Yes** to delete the user, press **No** to cancel **(Note: Deleted users cannot be recovered, but test reports completed by deleted users will be retained)**.

8.5.6.6 Editing User Permissions

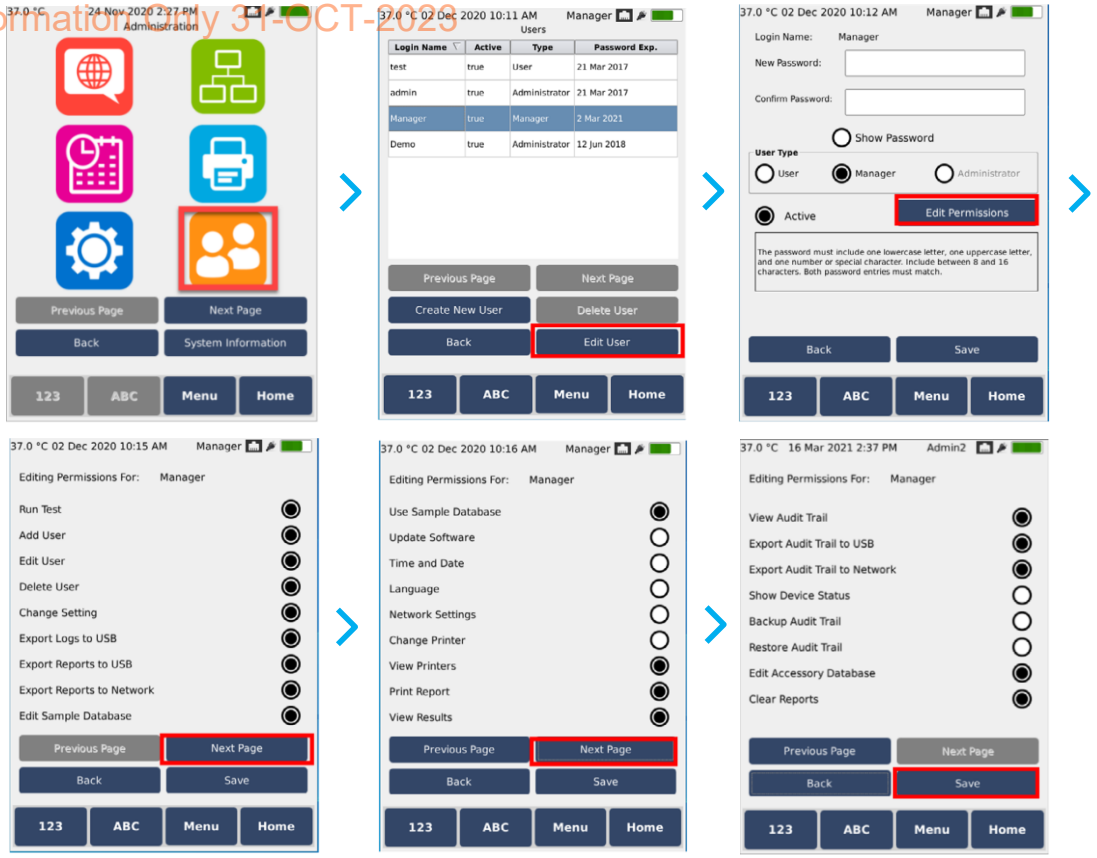
When *User Management* is **On**, the specific permissions of users can be modified. The table below outlines the default permissions for each user role. These permissions can be edited per user if that user has the **Edit User** permission enabled.

Default User Permission per User Type

Permission	User	Manager	Administrator
Run Tests	X	X	X*
Add User		X	X
Edit User		X	X
Delete User		X	X
Change Setting		X	X
Export Logs to USB		X	X
Export Reports to USB	X	X	X
Export Reports to Network	X	X	X
Edit Sample Database		X	X
Use Sample Database	X	X	X
Update Software			X
Time and Date			X
Language			X
Network Settings			X
Change Printer			X
View Printers	X	X	X
Print Report	X	X	X
View Results	X	X	X
View Audit Trail	X	X	X
Export Audit Trail to USB		X	X
Export Audit Trail to Network		X	X
View Machine Usage			X
Backup Audit Trail			X
Restore Audit Trail			X
Edit Accessory Database		X	X
Clear Reports		X	X

If administration can run tests is set to **No, the administrator cannot run a test*.

User Permissions



To modify the permissions of specific users:

1. Navigate to the **User** icon.
2. Select a Login Name and **Edit User**.
3. Select **Edit Permissions**.
4. Using the radio buttons on the right-hand side of the screen, select or deselect to modify the permissions for the user selected. Select **Next Page** to navigate through the pages of permissions.
5. Select **Save** when all desired permissions have been selected.
6. To return to the list of users, select the **Back** button.

Users that have had their permissions edited will be marked with an asterisk (*) in the list of users.

General Settings Page 3

Permission	Description
Run Tests	**Enabled** – Allows the user to run an assay on the instrument.
	Disabled – The user does not have permission to run an assay.
Add User	**Enabled** – Allows the user to create a new user to a user role that is equal to or lesser than the user logged in. A Manager role can only create a User role or Manager role, not an Administrator.
	Disabled – User does not have the permission to create a new user.

Edit User	**Enabled** – Allows a user to modify an existing user. This allows the user to reset the password of the selected user, edit the permissions associated with the selected user, disable a user, or change the user type. A Manager role cannot modify a user's role to become an Administrator role – only a Manager or User.
	Disabled – User cannot modify another user's permissions, status, password, or user type.
Delete User	**Enabled** – Allows a user to delete another user. All data associated with the deleted user will remain on the system. A user can only delete a role that is equal to or less than the role they are logged in as. For example, a Manager cannot delete an Administrator user type, but can delete another Manager user type or user type.
	Disabled – User cannot delete another user.
Change Setting	**Enabled** – Allows a user to modify administrator settings, such as enabling User Management, Sample Size Detection, or password security features.
	Disabled – User cannot modify settings under the Administrator settings.
Export Logs to USB	**Enabled** – Allows the user to export all logs from the instrument to a USB device, including the audit trail. The logs from the instrument may be requested for troubleshooting purposes.
	Disabled – User does not have permission to export the instrument logs to a USB device.
Export Reports to USB	**Enabled** – Allows the user to export the reports to a USB device as a PDF.
	Disabled – User does have the permission to export test reports to a USB device.
Export Reports to Network	**Enabled** – Allows the user to export test reports to a network location. The user logged in must have access to the network location and the instrument must be successfully connected to the network.
	Disabled – User does not have permission to export test reports to a network location.
Edit Sample Database	**Enabled** – Allows a user to add, modify, and delete samples from the sample database.
	Disabled – User does not have permission to create new samples, modify existing samples, or delete samples from the sample database.
Use Sample Database	**Enabled** – Allows a user to utilize the sample database to pre-load samples to an assay. The sample database must be populated by a user with the permission to do so before use.
	Disabled – User does not have permission to utilize samples from the sample database to pre-load an assay.
Update Software	**Enabled** – Allows a user to update the software on the instrument from a USB device.

	Disabled – User does not have permission to update the instrument's internal software from a USB device.
Time and Date	**Enabled** – Allows a user to set the time and date on the instrument. The Time and Date menu includes enabling Daylight Savings Time (DST), setting the Network Time Protocol (NTP), and the time zone.
	Disabled – User does not have permission to modify the time and date on the instrument or other menu items associated with the time and date.
Language	**Enabled** – Allows a user to set the language to be used on the system.
	Disabled – User does not have permission to modify the language on the system.
Network Settings	**Enabled** – Allows a user to enable the network adapter settings for Ethernet or Wi-Fi. This allows the instrument to connect to a network.
	Disabled – User does not have permission to enable or modify network adapter settings.
Change Printer	**Enabled** – Allows the user to set the default printer.
	Disabled – Does not allow a user to set the default printer.
View Printers	**Enabled** – Allows a user to view the available printers.
	Disabled – User cannot view available printers.
Print Report	**Enabled** – Allows a user to print a test report for completed assays to a network, USB, or other supported printer.
	Disabled – User does not have permission to print a report.
View Results	**Enabled** – Allows a user to view the results from a completed, aborted, or halted assay through the results screen.
	Disabled – User cannot view completed, aborted, or halted assays.
View Audit Trail	**Enabled** – Allows a user to review the audit trail.
	Disabled – User cannot review audit trail entries.
Export Audit Trail to USB	**Enabled** – Allows a user to export the audit trail to a USB device. The file will be available in the form of a PDF.
	Disabled – User does not have permission to export the audit trail to a USB device.
Export Audit Trail to Network	**Enabled** – Allows a user to export the audit trail to a network location. The instrument must be connected to the network and the user that is logged in must have Windows permission to access the network location. The audit trail will be in the form of a PDF.
	Disabled – The user does not have permission to export the audit trail to a network location.

Show Device Status	**Enabled** – Allows a user to view the device status through **System Information**. The device status provides information on the health of the instrument regarding the LEDs, the number of completed assays, and number of cartridges run.
	Disabled – User does not have the permission to view the device status through the **System Information** screen.
Backup Audit Trail	**Enabled** – Allows a user to back up the audit trail through the Audit Trail **Export/Backup/Restore** button. The audit trail can be backed up internally, to a USB device or to a network location. The instrument must be connected to a network and the user that is logged in must have permission to access the network location.
	Disabled – User cannot back up the audit trail; the Export/Backup/ Restore button will be greyed out.
Restore Audit Trail	**Enabled** – Allows a user to restore the audit trail from a previous backup. The audit trail must be backed up to an internal or external location prior to restoring.
	Disabled – User does not have the permission to restore a backed-up audit trail.
Edit Accessory Database	**Enabled** – Allows a user to modify or add accessories to the accessory database.
	Disabled – User does not have permission to modify or create accessories in the accessory database.
Clear Reports	**Enabled** – Allows a user to clear and restore reports in **General Settings**. Clearing reports will delete reports from the **Test Results** screen.
	Disabled – Does not allow users to clear or restore reports.

8.5.7 *Calibrate Touchscreen*

This section describes how to calibrate the touchscreen of the Endosafe® nexgen-PTS™ instrument. The instrument is calibrated by the manufacturer prior to shipment, which includes calibration of the touchscreen and thermal calibration of the instrument. In the unlikely event that the touchscreen requires recalibrating, follow the screen prompts. This should be performed only if it is absolutely necessary. Once the touchscreen is recalibrated, the instrument will reboot.

	The touchscreen calibration is very sensitive. It is highly recommended that an experienced technician performs the calibration using a stylus or a pipette tip. Be sure to be as precise as possible when calibrating.

To recalibrate the nexgen-PTS™:

1. Select the **Calibrate Touchscreen** button. **(Note: If User Management is turned on, only an Administrator can select this button.)**
2. A prompt will display, *"This will configure the touchscreen and reboot the instrument. Is this what you want?"* Press **OK** to continue or press **Cancel** to cancel the calibration.
3. System will reboot and enter the touchscreen calibration screen.

4. Follow the prompts displayed on the screen.
5. One crosshair will display in each corner and the middle of the screen. Select the center of the crosshair as indicated on the screen as accurately as possible.
6. The instrument will reboot.

Calibrate Touchscreen

8.5.8 *System Information*

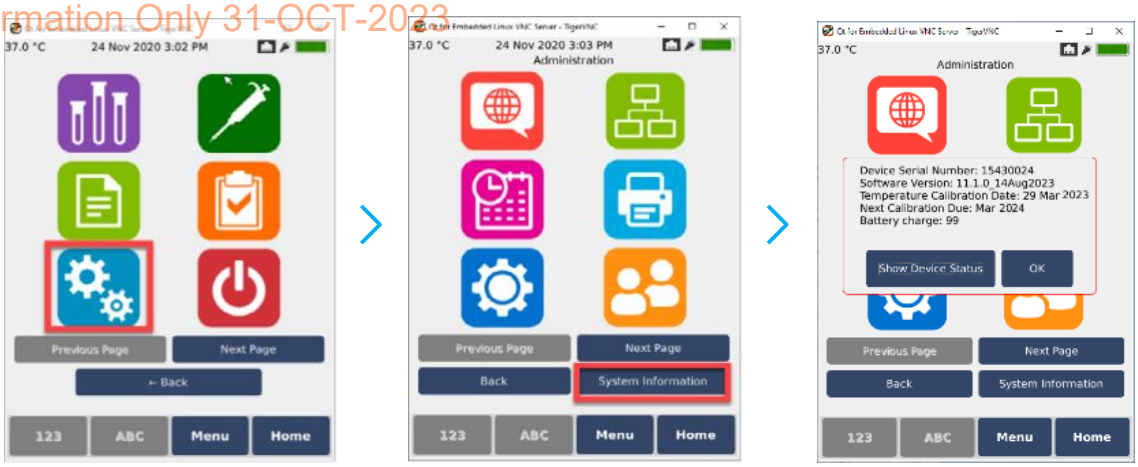
All user types can select the **System Information** button and view information about the instrument. This icon displays the *Device Serial Number, Software Version, Temperature Calibration Date, Next Calibration Due, and Battery Charge percent*. The system information will be required when scheduling service or troubleshooting with a Charles River Laboratories' Technical Services Representative.

The system information displays the due date for the next temperature calibration. Temperature calibration should be scheduled annually through Charles River Laboratories or a representative.

The **Show Device Status** button can be used to display the device status, which contains information used by Charles River Laboratories' Technical Services Representatives.

To access the *System Information* screen:

1. Select the System Information button on the **Administration** screen.
2. Select the **Show Device Status** button.
3. A **Device Status** window will display the instrument status report.
4. If a printer is configured, select the **Print** button to print the report.
5. When done reviewing system information, select the **OK** button.



8.6 Shutdown

To power off or restart the instrument, select the **Shutdown** icon from the **Menu** screen. Selecting the **Shutdown** icon will display a window to *Cancel, Power Off, or Restart* the instrument. To power down the instrument, select **Power Off** or quickly press and release the **Power** button located on the back of the instrument.

The system is shut down when the screen is blank and the waves are not illuminated. The recommended method to power down the instrument is through the **Shutdown** icon, as holding down the power button on the rear of the instrument can result in a hard reset of the instrument.

⚠	**DO NOT** hold down the power button on the rear of the instrument to regularly power down the instrument. If the instrument is operating normally, utilize the **Shutdown** icon on the instrument. If the instrument becomes unresponsive, force a shutdown by holding down the **Power** button for five seconds.

From the display window, select the option you wish to pursue:

- **Cancel** – Closes window and does not power down the instrument.
- **Power Off** – Powers down the instrument. The back power button will need to be pressed to turn the instrument back on.

- **Restart** – Powers down the instrument. Once the instrument has completely powered off, it will turn back on.

Shutdown (Power Off/Restart)	Mechanical Power Button
	

8.7 USB Device

USB Devices (Data Only)

This section describes how to connect a USB device, save log file(s), save test report(s), and update software from a USB device. To access USB devices, select the **USB Devices** icon from Page 2 of the Menu. All test reports saved to the USB device from the Endosafe® nexgen-PTS™ will be saved as .pdf (Portable Document Format). The USB device must be a FAT32 device type. If the device inserted is not in the list, select **Refresh USB Devices**.

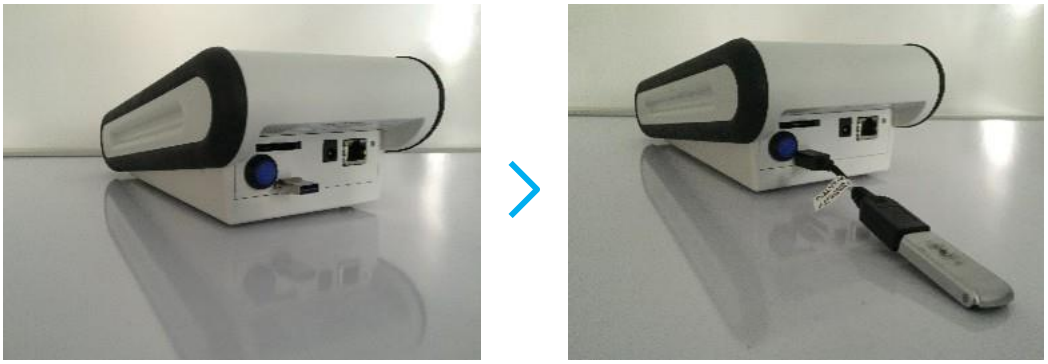
Navigating to USB Devices Menu

	To set up a USB printer, see section 8.5.4.1.

8.7.1 *Inserting a USB Device*

A male Micro-USB (type B) device can be directly plugged into the female Micro-USB (type B) port on the rear of the instrument. To communicate with standard USB type A devices (such as a flash drive), use the USB type A adapter cable included with the device.

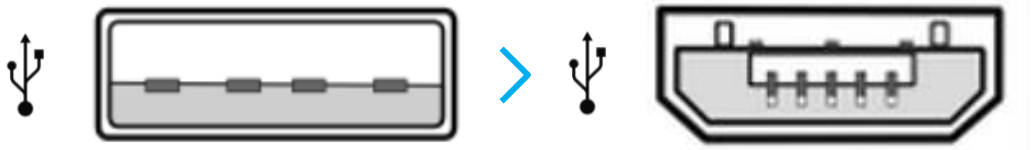
Inserting a USB Device



USB B micro male direct connected device (USB flash drive shown)

USB (type A) adapter to USB (type A) device (USB flash drive shown)

USB Connecter(s)



USB (type A) male connector

Micro-USB (type B) male connector

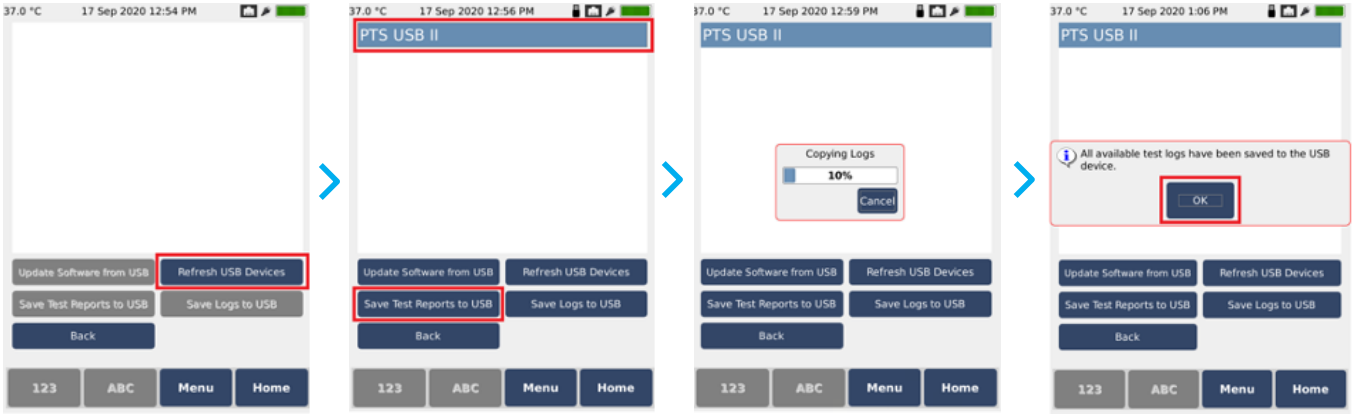
8.7.2 *Saving Log Files to a USB Device*

If *User Management* is **On**, only an Administrator or Manager account can save logs to a USB Device.

To save logs to a USB device:

1. Insert the USB type A device using the USB type A adapter or connect the Micro-USB device directly to the unit.
2. Press the **Refresh USB Devices** button if the device is not displayed.
3. Select the device from the **Menu** (buttons for Save Logs to USB, Save Test Reports to USB, and Update Software from USB will be grayed out until a USB device is selected). Press the **Refresh USB Devices** button if the device is not displayed.
4. Press the **Save Logs to USB** button.
5. A status bar will appear indicating what portion of the Log files have been saved. Once the bar reaches 100%, a dialog will appear confirming successful transfer to the USB device. Press **OK** to exit the dialog.

Saving Log Files to a USB Device



8.7.3 *Saving Test Report Files to a USB Device*

All user types can save test report files to a USB device.

To save test report files to a USB device:

1. Insert the USB type A device using the USB type A adapter or connect the Micro-USB device directly to the unit.
2. Press the **Refresh USB Devices** button if the device is not displayed.
3. Select the device from the **Menu** (buttons for Save Logs to USB, Save Test Reports to USB, and Update Software from USB will be grayed out until a USB device is selected).
4. Press the **Save Test Reports** to USB button.
5. A status bar will appear indicating what portion of the reports has been saved. Once the bar reaches 100%, a dialog will appear confirming successful transfer to the USB device. This may take several minutes. Once the transfer is complete, press OK to exit the dialog.

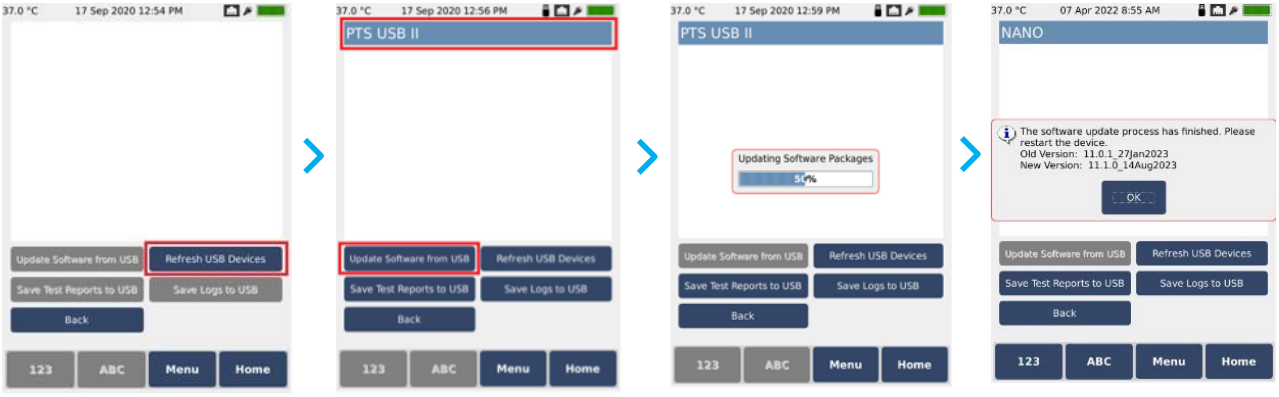
Saving Log Files to a USB Device

8.7.4 *Updating Software with USB*

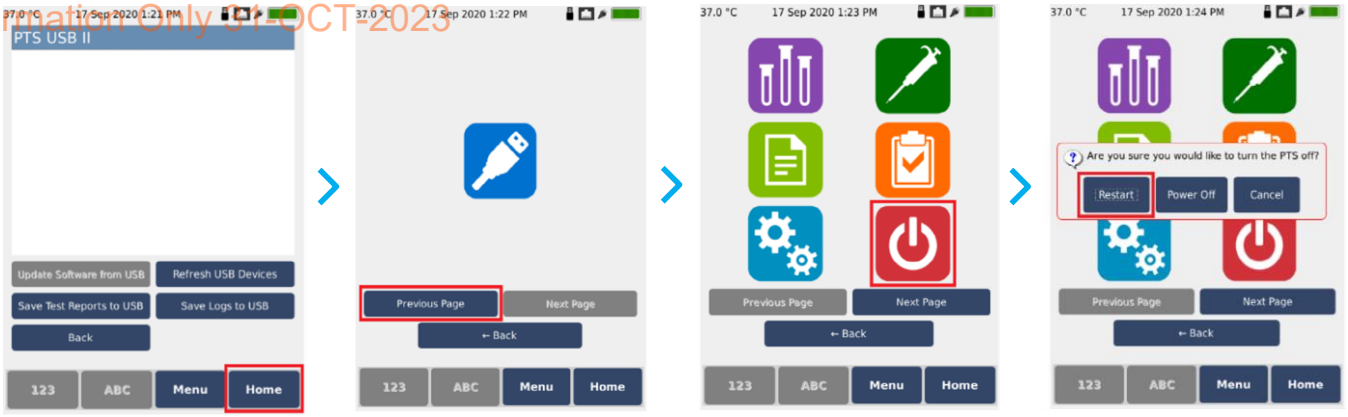
If *User Management* is **On**, only an Administrator or Manager account can update software from a USB device.

1. Insert the USB type A device containing the update package using the USB type A adapter or connect the Micro-USB device containing the update package directly to the unit.
2. Press the **Refresh USB Devices** button if the device is not displayed.
3. Select the device from the **Menu** (buttons for Save Logs to USB, Save Test Reports to USB, and Update Software from USB will be grayed out until a USB device is selected).
4. Press the **Update Software** from USB button.
    a. Software updates will require approximately five minutes.
    b. If the USB device does not contain software, the system will display an error message and will not update.
    c. Once the upgrade is complete, a dialog box will appear confirming successful update along with a reminder that the unit must be restarted for the changes to go into effect. Press **OK** to exit the dialog.

Updating Software with USB



5. Restart the instrument.
    a. To restart the instrument, navigate back to the Main Menu and select the **Shutdown** icon. Press the **Restart** button once the shutdown dialog appears.



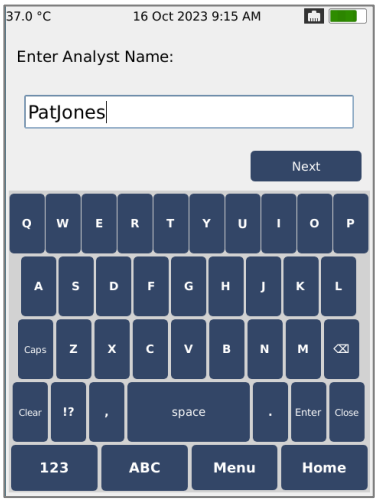
9 RUNNING AN ASSAY

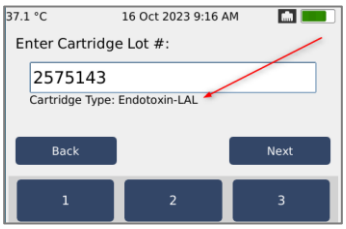
This section reviews how to run an assay. Before you get started, you will need:

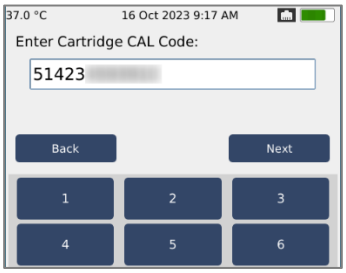
- **Cartridge Lot Number** and **Calibration Code** values for the cartridge used in the assay.
- **Sample Name** and **Dilution** or **Concentration** factor for the sample used in the assay.
    a. Optional: **Sample Lot Number** and **Endotoxin Limit** values.

To begin an assay, from the **Main Menu** navigate to the **Assay** page by selecting the **Menu** button which toggles between the Assay and Main Menu screens. The Assay page should display the message “Insert Cartridge”.

1. Insert a cartridge into the instrument’s cartridge bay slot.
    a. To access the cartridge bay, lift the front cover on the instrument.
    b. Take care to only touch the curved end of the cartridge; avoid touching any other part of the cartridge including the reservoirs.
    c. Insert the cartridge firmly into the slot of the bay with the reservoirs facing up.
2. Enter **Analyst Name** using the on-screen keyboard and select **Next**.
3. Enter **Cartridge Lot #** and select **Next**.
    a. Use the Back button to return to the previous screen.
    b. Once the full Lot Number value is entered, the Cartridge Type detected by the system will display under the field.
4. Enter **Cartridge CAL** (Calibration) **Code** and select **Next**.
    a. If another cartridge from the same Lot has been used in a previous assay on the instrument and the assay has not been cleared from the instrument’s database, the system will auto-fill the

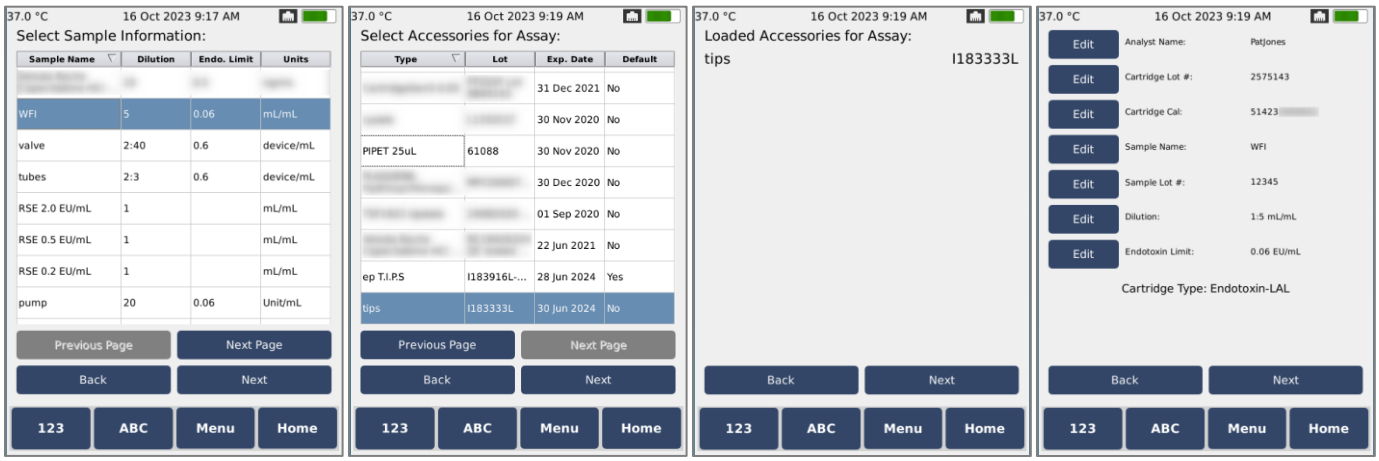




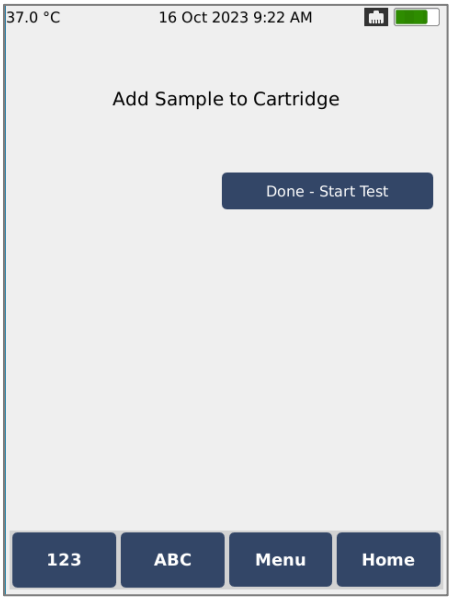


Cartridge CAL Code field; if the auto-filled value is incorrect, clear the field and enter the correct value.

5. Select a **Sample** record from the sample database and choose **Next**.
    a. To add a new sample during configuration, do not select a sample record; instead, select **Next** which will guide the user through several screens to enter sample details beginning with the **Sample Name, Sample Lot #, Dilution** or **Concentration** factor, and **Endotoxin Limit**.
    b. Please note, adding new sample details during configuration will not create a new record in the sample database. To create a new record in the sample database, see 8.1.1 Creating a New Sample.
6. Select an **Accessory** record from the accessory database and choose **Next**.
    a. Users are not required to assign any accessories to the assay; to skip this step, simply choose **Next**.
7. Review the list of assigned accessory record(s) to confirm selection(s) are correct and select **Next** when ready.
    a. If no records were assigned to the assay, the list will read “N/A”.
8. Review the Assay Properties to confirm all is correct. Use the **Edit** button next to each line item to make any changes. To move forward, choose **Next**.



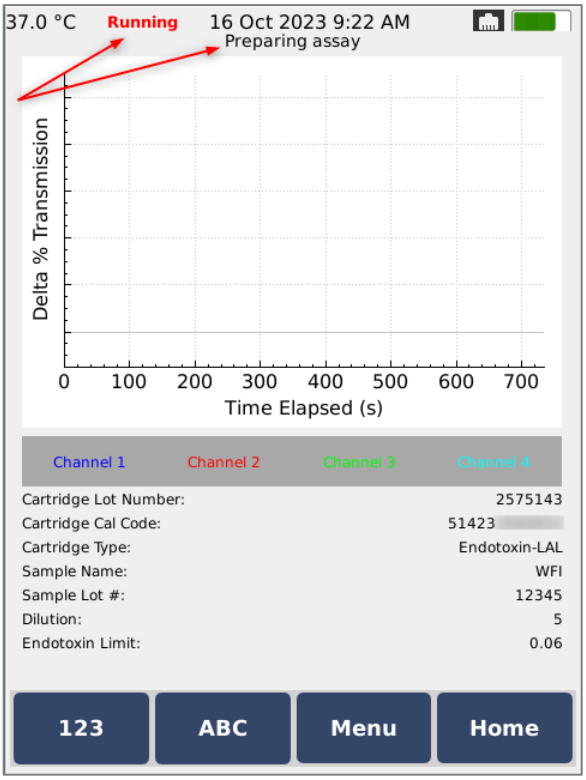
9. **Add Sample to Cartridge**: Add sample material to each reservoir of the cartridge (25 µL) and select **Done – Start Test** to begin the assay.
    a. Lift the front cover on the instrument to access the cartridge currently in the instrument’s bay.
    b. *Hold the pipette so the tip is at an angle and take care the pipette does not touch the sides or bottom of the reservoir well*. Holding the pipette vertically or allowing it to touch the sides or bottom of the well may result in sample being forced into the channel too early and result in an invalid assay.
    c. Avoid using techniques which cause splash out or bubbles in the reservoir well. Splash out will result in inaccurate sample volume and bubbles may interfere with test readings, both of which may result in an invalid assay.

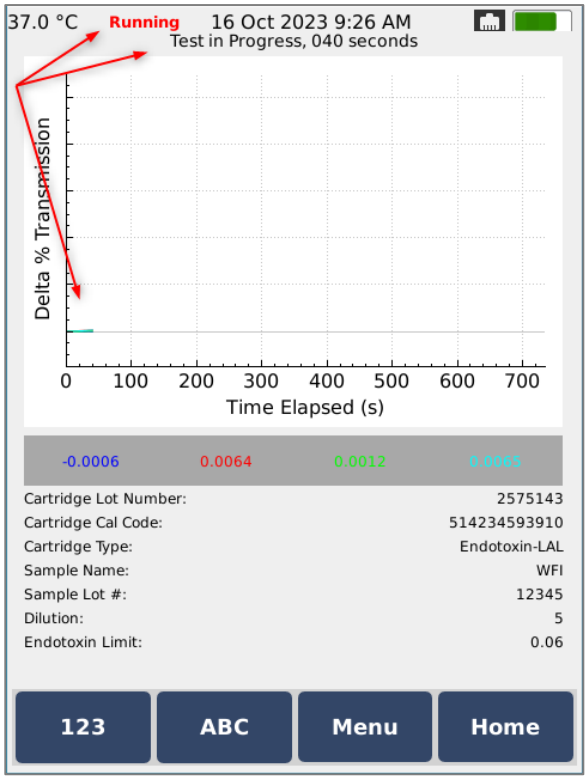


10. **Assay in Progress**

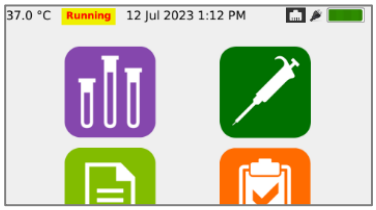
a. **Preparing Assay**: First, the system will perform a series of procedures to prepare the assay for testing: drawing sample, mixing, filling test wells, and settling. While the instrument performs these steps, the Assay Status will read “Preparing Assay”.

b. **Test in Progress**: Once the assay preparation is complete, the testing will begin. The assay status will now read “Test in Progress” with a count (in seconds) of how long the test has been in progress.





c. Should users navigate away from the Assay screen, the “Running” message in the notification bar will persist while assay is in progress to alert users.



d. When finished, the **Test Results** will display on the screen.

11. Review Test Results.

a. For more information on interpreting, saving, or printing test results, see 8.3 Results.

12. Remove cartridge from the instrument bay to begin a new assay.

10 TROUBLESHOOTING

This section describes how to troubleshoot some of the more common issues and error messages that a user could encounter when operating the Endosafe® nexgen-PTS™ instrument. This is not a comprehensive guide but is meant as a starting point before contacting the Charles River Laboratories Technical Services Department. If an issue is encountered that is not covered in the troubleshooting procedure or an issue persists, please contact the Technical Services Department.

	To expedite troubleshooting, please provide Charles River Technical Services with the logs from the instrument.

Troubleshooting Guide

Symptom	Probable Cause	Correction
Screen is not displaying, and the blue wave is not illuminated.	The instrument is not on.	Turn on the instrument.
	Batteries are fully depleted.	Connect the instrument to the power supply for one hour prior to restarting the instrument.
	System is unplugged with low battery power.	Connect the instrument to the power supply and turn on. Wait until instrument recharges prior to disconnecting it from the power source.
Screen is not displaying,	System is booting up.	Wait for instrument to boot up.

Symptom	Probable Cause	Correction
but blue wave is illuminated.	System needs to be restarted.	If instrument is connected to power, unplug. Hold the Power button in the rear of the instrument down for five seconds. Plug the instrument into the power supply and turn on the power and wait for the system to restart.
System reboots without user prompt	Batteries are critically low.	Recharge batteries before disconnecting the instrument from power. (Note: The instrument will attempt to notify the user if the instrument is going to shut down because of low battery.)
Pressing Next after entering the calibration code does not allow user to move to the following screen.	Calibration code was entered incorrectly.	Check calibration code against documentation. Correct the calibration code.
Pressing Next does not work after the lot number is entered.	Lot number was entered incorrectly.	Check lot number against documentation. Correct the lot number.
Touchscreen is not working.	Boot-up error.	Shut down the instrument using the manual Power button. Restart the system once the power is off.
When a touchscreen button is pressed, the response on the screen does not match.	Touchscreen is not calibrated.	The Administrator will need to run the touchscreen calibration, as described in section 8.5.7.

10.1 Error Messages

This section describes the process for editing, reviewing, and adding information to the **Sample Database**. To access the Sample Database, select the Sample Database icon from the **Menu** screen.

Error Message - Cartridge	Probable Cause	Correction
"Used cartridge detected. Remove and reinsert a new cartridge."	Cartridge has previously been used and is not blank.	Debris is on the cartridge.
	Debris is on the cartridge.	Remove debris or use a new cartridge.

Error Message - Cartridge	Probable Cause	Correction
"Interrupter LED failed. Remove cartridge and reinsert to retry."	An error was encountered when checking the cartridge.	Remove the cartridge and wait for prompt to insert cartridge. Retry cartridge. If issue persists, try a new cartridge. If issue persists after multiple cartridges, contact Charles River Laboratories Technical Services Department.
	Debris is on the cartridge.	Remove debris or use a new cartridge. Debris interferes with the interrupter LEDs. If issue persists after multiple cartridges, contact Charles River Laboratories Technical Services Department.
"UV LED adjust failed. Remove cartridge and reinsert to retry."	An error was encountered when checking the cartridge.	Remove the cartridge and wait for prompt to insert cartridge. Retry cartridge. If issue persists, try a new cartridge. If issue persists after multiple cartridges, contact Charles River Laboratories Technical Services Department.
"UV Intensity failed. Remove cartridge and reinsert to retry."	An error was encountered when checking the cartridge.	Remove the cartridge and wait for prompt to insert cartridge. Retry cartridge. If issue persists, try a new cartridge. If issue persists after multiple cartridges, contact Charles River Laboratories Technical Services Department.
"No sample detected in one or more channels. Remove and inspect cartridge."	Sample was not added to a channel.	Remove the cartridge, use a new cartridge, and retest. Ensure that sample is pipetted correctly to all four sample wells.
	Pump is not drawing sample into channel.	Ensure the cartridge is inserted fully. If the issue persists, notify Charles River Laboratories Technical Services Department.
“Detected sample size is too small.”	Sample size in well was not within the range required for the test.	Review sample size configurations to confirm it is set up properly. Repeat test using a new cartridge.
“Detected sample size is too large.”	Sample size in well was not within the range required for the test.	Review sample size configurations to confirm it is set up properly. Repeat test using a new cartridge.

Error Message - Cartridge	Probable Cause	Correction
"Sample detected early in Optical Well. Remove cartridge and reinsert new cartridge."	Sample was not drawn into optical well correctly.	Repeat test using a new cartridge.
"Temperature too low. Instrument is below the required temperature range."	Batteries are critically low.	Plug instrument into power supply for one hour prior to restarting the instrument.
	System temperature is too low.	Restart instrument and verify, in the upper left-hand side of the touchscreen, that the temperature is increasing. If error occurs again, repeat.
	System temperature is too low – component issue.	Restart instrument and observe the temperature in the upper left-hand side of the touchscreen. If the temperature is not increasing (or is not able to get to 37 °C in 10 minutes), contact Charles River Laboratories Technical Services Department.
"Temperature too high. Instrument is above required temperature range."	System temperature is too high.	Confirm that the room temperature is within specifications and that the fan is not blocked in the back of the instrument.
	System temperature is too high – component issue.	Contact Charles River Laboratories Technical Services Department.
“Failed to start the heater. The device cannot reach the required temperature.”	An error was encountered at instrument startup.	Restart instrument. Contact Charles River Laboratories Technical Services Department if issue persists.
"Battery charge status cannot be read. Initialize PTS system to retry."	An error was encountered at instrument startup.	Remove the cartridge and wait for prompt to insert cartridge. Retry cartridge. If issue persists, try a new cartridge. If issue persists after multiple cartridges, contact Charles River Laboratories Technical Services Department.
"Low battery. Please connect the device to a charger."	The battery level is getting low and is at risk of shutting down.	Plug instrument in using the external power supply as soon as possible. Recharge the batteries prior to removing the instrument from the power connection.

Error Message - Cartridge	Probable Cause	Correction
"Extremely low battery. Connect to charger or shut down."	The battery level is getting very low and is at high risk of shutting down.	Plug instrument in using the external power immediately. Recharge the batteries prior to removing the instrument from the power connection.
"An improper shutdown was detected. For future shutdowns, please use the software function to turn off the system, and if running the unit on battery, please ensure adequate charge."	Power button held down too long.	Review manual section on Shutdown (section 8.6). To get a proper shutdown, the Power button should not be held for more than a second.
	Battery level too low.	Plug instrument in using the external power immediately. Plug instrument into power supply for one hour prior to restarting the instrument and keep plugged in to get to a full charge.
Temperature and battery level are never displayed.	An error was encountered at instrument start-up.	Restart instrument. Contact Charles River Laboratories Technical Services Department if issue persists.

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