



User Manual

for Accellix Software Version 3.9.0

SPC-062 Revision 08

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1. About the Accellix Platform

The Accellix Platform revolutionizes flow cytometry by offering a simplified and automated workflow. The automated benchtop flow cytometer and pre-packaged and disposable cartridges opens up flow cytometry capabilities to a wider audience by replacing previously complex workflows. Instead of relying on highly trained individuals for assay preparation, sending samples to centralized labs, and professional flow cytometry analysts for data interpretation, Accellix streamlines and eliminates many of these steps, offering a fast, cost-effective, and efficient solution to obtain consistently reliable flow cytometric results in just 30 minutes—from automated sample preparation through to complete analysis—right in their labs.

For researchers and product developers across the biotechnology industry, the Accellix Platform is a flexible system to streamline the development of customized assays. The compact design of the instrument makes it ideally suited for point-of-need (PON) applications, seamlessly integrating into biologics manufacturing as an in-line analytical technology. Additionally, in the growing field of immunotherapy, Accellix plays a pivotal role in quality assurance and quality control (QA/QC) processes, reducing the time and costs associated with cellular sample processing while increasing reproducibility to ensure consistent and reliable outcomes.

In summary, the Accellix Platform automates and simplifies sample preparation, offering a user-friendly interface and reliable results through the use of single-use cartridges. The automated workflow increases reproducibility while reducing the reliance on trained professionals to provide powerful insights and reliable data for rapid decision-making to drive scientific innovation across the industry.

2. Intended Purpose

This document provides instructions for operating the Accellix Instrument. Refer to the relevant Technical Data Sheet and Instructions for Use for instructions related to the Accellix cartridges and associated assay reagents. The Accellix Platform is intended to perform the flow cytometric measurement of analytes in biological samples using assay cartridges designed specifically for use with the Accellix Instrument. In addition to supporting rapid assay development, Accellix facilitates rapid assay development for applications requiring customized assays, such as cell engineering, and is well-suited as an automated quality control (QC) tool for biomanufacturing.

Two types of assays have been developed for the Accellix:

1. **Off-the-shelf assays:** Accellix provides a range of generic assays that are widely used throughout research and development of cell products. This includes the T cell panel for monitoring T lymphocyte populations, the TBNK panel for general lymphocyte populations and the stem cell panel for monitoring hematopoietic stem cell populations.
2. **Customized assays:** The flexibility of the Accellix Platform enables the migration of user-specific assays onto the instrument. Through a joint development process, customized cartridges can be developed based on the user's specific needs. For example, customized assays can be developed to streamline the QC monitoring process for manufacturing and releasing cell therapy products.

3. Principles of Operation

The Accellix Platform utilizes the general principles of flow cytometry, and integrates fluidic, optical, and electronic systems to measure and analyze optical and fluorescence characteristics of cells or other particles of interest.

Accellix enables the automation of the following three steps in the flow cytometry process:

1. **Biochemical sample preparation** (e.g., the assay): Accellix automates the preparation of the assay, ensuring consistent and reliable sample handling.
2. **Flow cytometric data acquisition**: The platform automates the acquisition of flow cytometric data, providing precise and high-throughput analysis of samples.
3. **Reporting and data acquisition**: Accellix reports detected events in a format that readily permits further analytical data processing. Users have the option of using algorithm-based auto-analysis of cell populations or manual analysis.

In rare instances, inaccurate results may occur due to incorrect usage of the instrument. The instrument should be used in strict accordance with this User Manual.

The Accellix platform is designed to enable an automated flow cytometry workflow, greatly simplifying the operational process. This enables individuals with limited laboratory experience to operate the platform effectively, without specialized skills or the need for extensive training.

3.1. Mode of Operation

The following steps describe the mode of operation of the Accellix system:

1. **Cartridge Selection**: The user selects the appropriate cartridge for the desired assay.
2. **Sample Introduction**: The user introduces assay specimen into the Accellix Cartridge following the specific instructions provided in the Technical Data Sheet and Instructions for Use. The cartridge is then closed to create a closed system.
3. **Assay Initiation**: The user taps the **Start** icon on the Accellix Instrument touch screen to initiate the assay process.
4. **Instrument Prompts**: The user follows the step-by-step instructions displayed on the instrument touchscreen.
5. **Cartridge Insertion**: The user opens the Accellix Instrument door, inserts cartridge, and closes the instrument door.
6. **Cartridge Identification**: The instrument automatically reads the identifying data for the cartridge (cartridge type, lot number, serial number, etc.) from the QR code on the cartridge.
7. **Sample Information Entry**: The user is prompted to enter a sample ID and kit number (note that the kit number may not be configured for all instruments). This information can be entered using the instrument's on-screen keypad, an external keyboard connected via USB port, or a barcode scanner.
8. **Sample ID Confirmation**: The user confirms that sample ID and cartridge type are correct before proceeding to run the assay.
9. **Progress Display**: An on-screen progress display shows the estimated time remaining until the completion of the assay.
10. **Automated Assay Execution**: The assay proceeds automatically, including the execution of the flow cytometric reading and analysis of the data acquired.

11. **Completion Notification:** Messages are displayed on the instrument screen to notify the user when the assay has been completed.
12. **Data Handling and Results:** Depending on the specific assay and the instrument configuration, the analyzed data may be copied to a file location in the instrument memory or on an attached external drive. If relevant, a results screen is displayed, and a printout is automatically issued (See Technical Data Sheet for the outcome designated for a specific test type.).
13. **Cartridge Removal and Disposal:** Once the assay is finished, the user removes the single-use cartridge from the instrument and disposes of it in a biohazard waste receptacle.
14. **Instrument Reset:** Once the instrument door is closed, the instrument screen returns to the **Home** screen, and the next assay can be started.

4. Overview of Operating Elements

The Accellix Platform consists of three components, including a benchtop flow cytometer instrument, a single-use cartridge, and customizable analysis software available separately.

The Accellix Instrument is operated using the touchscreen display, shown in Figure 1.



Figure 1: The Accellix Instrument

An image of the front (Figure 2) and an illustration of the back (Figure 3) of a single-use Accellix cartridge are displayed below. The Technical Data Sheet accompanying each Accellix assay gives a detailed description of how to use each specific Accellix cartridge type.

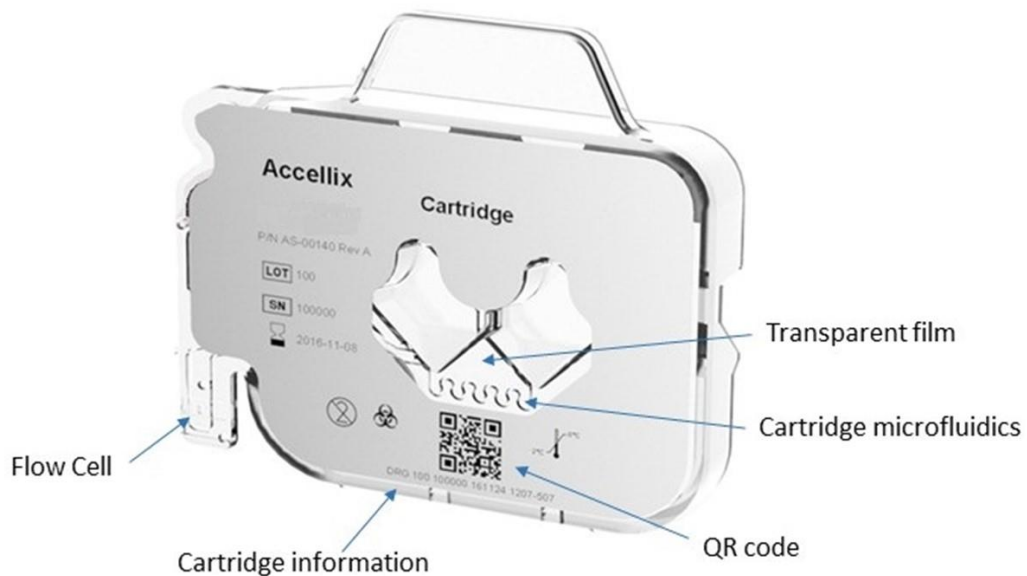


Figure 2: Image of an Accellix cartridge, as viewed from the front surface.

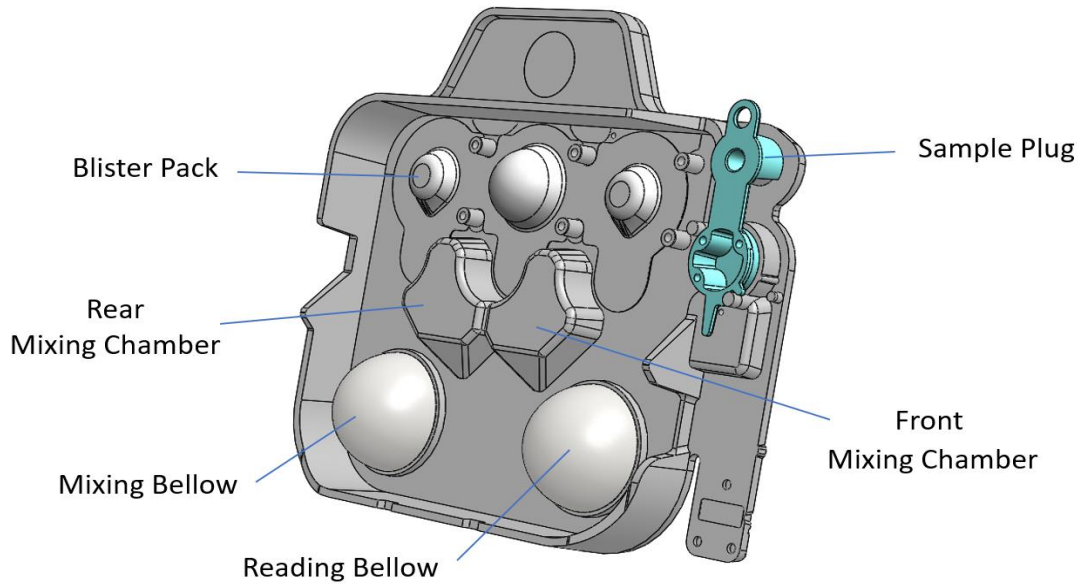


Figure 3: Illustration of an Accellix cartridge, as viewed from the rear surface.

5. First Time Installation

5.1. Product Contents

PART #	DESCRIPTION	QTY.
AS-00150	Accellix Flow Cytometer	1
CS-00070	Biohazard Bag	1
CSE-00624	WiFi Antenna	1
CSE-00680	Power Supply Cable (interchangeable for multiple geographical regions)	1
CSE-00551	Ethernet Cable	1
CSE-00693	USB 3.0 32GB DOK for User Manual	1
CSF-00578	Vortex Foam Adapter	1

The unpacking and installation of the Accellix Instrument should only be performed by an Accellix Field Application Scientist to ensure proper setup.

Contact Accellix support to confirm whether the shipping case can be returned to the manufacturer or to get specific instructions for proper disposal.

5.2. Installation of Computer Hardware

Computer hardware components can be connected to the Accellix instrument using the ports on the rear panel (Figure 4).

Certain components such as the power cable, Ethernet network cable, and/or printer-USB cable, will be connected by an Accellix Field Application Scientist at the time of initial instrument installation.

For certain assays, the data files generated are intended to be copied to a user-selected destination. Users can connect an external drive at one of the four USB ports located on the rear instrument panel to copy the data files.

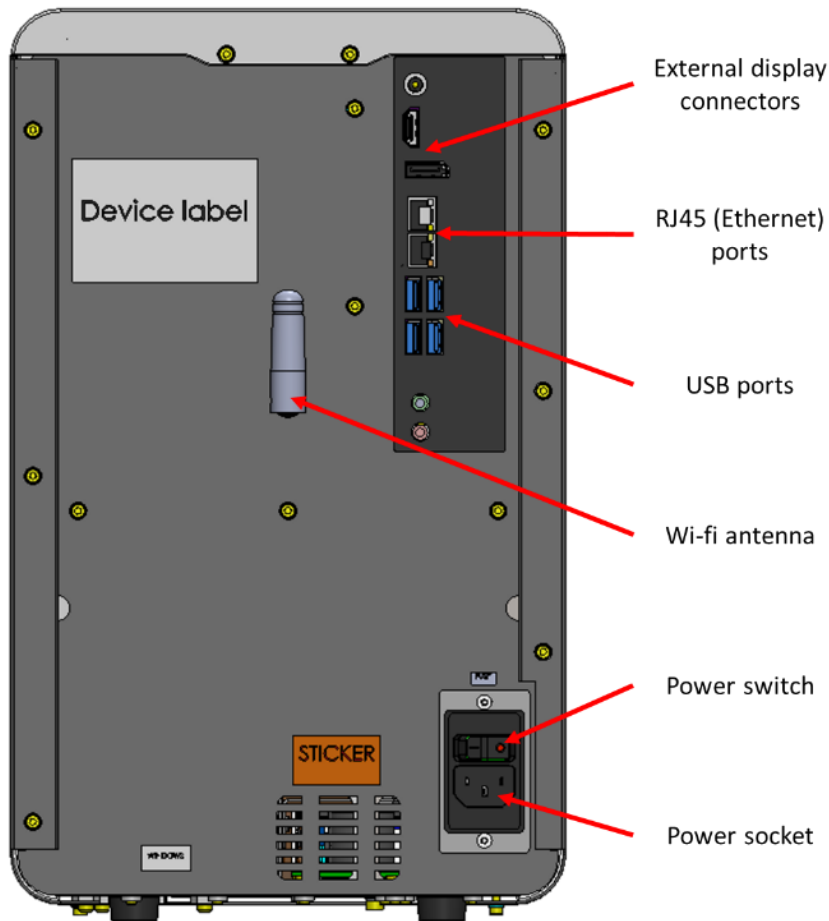


Figure 4: View of rear panel of Accellix Instrument

The following are connections that can be made to the Accellix Instrument with hardware components:

1. **Internet connectivity:** To connect the instrument to the internet using a network cable, an ethernet network cable should be connected to the RJ-45 port at the rear of the Accellix Instrument (Connection should be performed using a network cable less than 3 meters or less). Alternatively, the instrument can be connected to the internet via Wi-Fi.
2. **External memory drive:** A flash drive or external hard drive can be connected to the Accellix Instrument using one of the four USB ports located on the rear panel.
3. **Printer connection:** A printer can be connected using the printer-USB cable inserted into one of the USB ports on the rear of the instrument, or by connecting to a network printer by using an ethernet cable or through a Wi-Fi connection.
4. **Peripherals:** If needed, e.g., for troubleshooting or touchscreen issues, a mouse and/or keyboard can be connected to the instrument using one of the USB ports on the rear panel of the instrument.
5. **Barcode scanner:** An external barcode scanner, e.g., for automatic input of the sample ID, can be connected to the instrument at one of the USB ports on the rear panel of the instrument.

6. User Logins

Note: In order for the Accellix Platform to support 21 CFR Part 11 compliance, the login feature must be set to “on”.

If an instrument is configured to require user logins, the **User Login** screen (Figure 5) is displayed when the instrument starts up.

If user logins are not required, the instrument will start up as described in Section **13 Operating the Accellix Platform**.

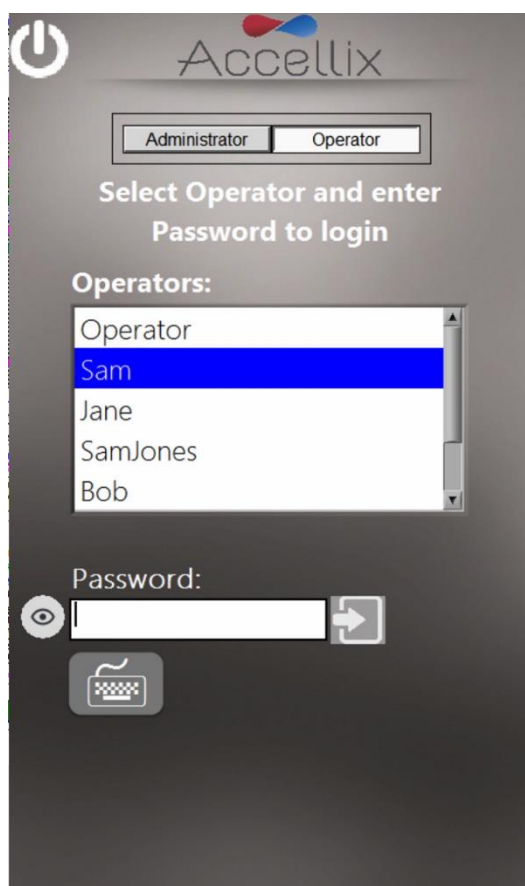


Figure 5: The User Login screen


There are two types of user personas with distinct capabilities: **Operators** and **Administrators**.

Log in as an **Operator** in order to run an assay.



Log in as an **Administrator** to have additional privileges to perform the following tasks:

- Create and manage new users
- Configure login options
- Set system parameters (see Section **12 Administrator Settings**)
- Copy, edit, print or export the audit trail
- Set various parameters including backup location, what files to copy when backing up, deleting old data, view errors, etc.

6.1. To Login

1. Select a user from the list.
2. Enter selected user's password.
3. Tap the **Log in** icon  or hit the **Return/Enter** key on the keyboard.

Note: Tapping the **Keyboard** icon  will display a virtual on-screen keyboard.

Once the correct password has been entered, the **Change Password** icon  and the **Next** icon  appear.

6.2. To Change Password

1. Tap the **Change Password** icon . The **Change Password** screen (Figure 6) is displayed:

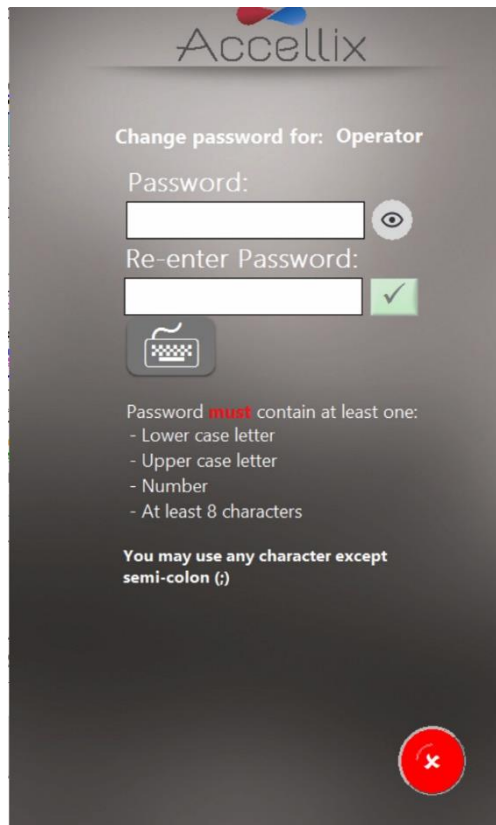





Figure 6: Change Password screen

2. Enter the new password twice, identically.
 - a. Press the eye () icon to show or hide the password
 - b. Press the cancel icon () to not change the password

The **Ok** icon  will only become active when the following password conditions are met:

- Both passwords entered must be identical
- Minimum password length is 8 characters
- Other configured password requirements

The following configurable password requirement options apply:

- The password must contain at least 1 upper-case letter
- The password must contain at least 1 lower-case letter
- The password must contain at least 1 number

See Section **8.3 To Change Parameters** to see how to configure these options.

Note: The password may contain a symbol (e.g., #@%, etc.) except for a semi-colon (;)

Note: The system also checks password history to ensure that a new password has not been previously used by the same user.

3. Tap the **Next** icon to display the **Home** screen (Figure 16).

Note: The **Home** screen will now have a **Log out** icon  in the top right-hand corner.

7. Main Administrator Screen

When an Administrator logs in, the **Main Administrator** screen (Figure 7) is displayed:

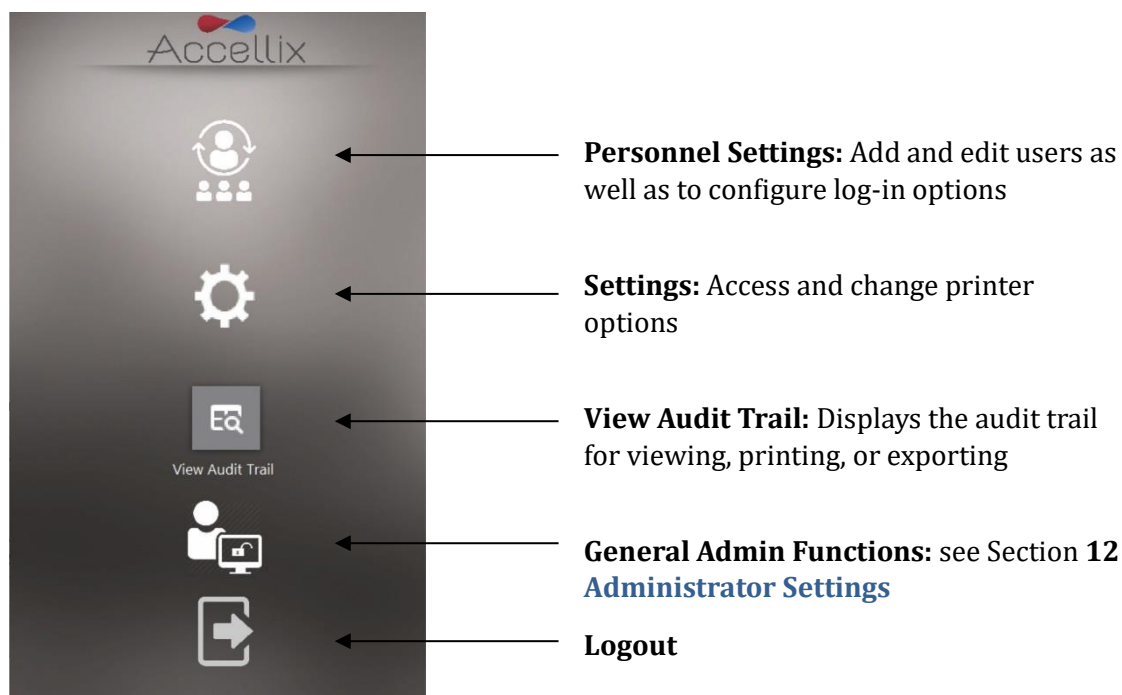


Figure 7: Main Administrator screen

Note: Depending on how your system is configured, the **General Administrator** icon may or may not be visible.

8. Personnel Settings

8.1. To Edit Users and Log In Options

1. Tap the **Personnel** icon . The **Personnel** screen (Figure 8) is displayed:

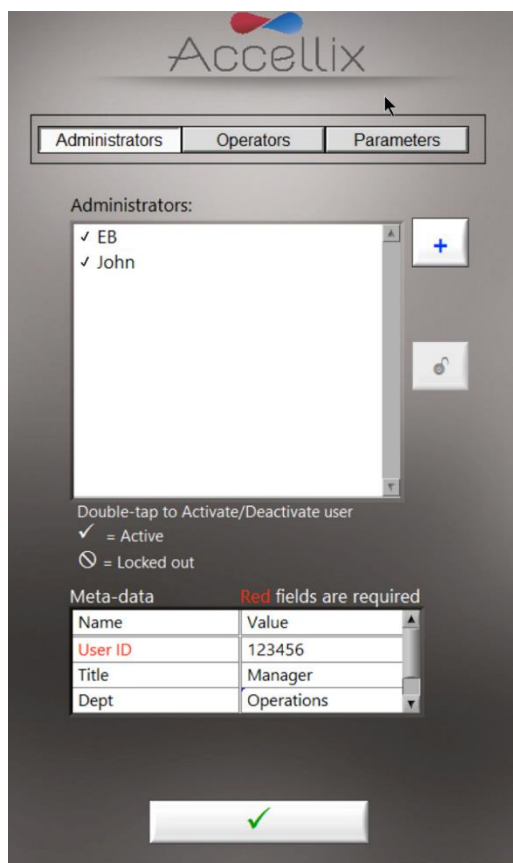






Figure 8: Personnel screen showing example Admin Users with Example Meta-data

The **Personnel** screen has three options across the top: **Administrators**, **Operators** and **Parameters**. When either the **Administrators** or **Operators** is selected, the software allows for the addition, unblocking, activating, or deactivating of a user. In addition, any meta-data, such as their personal information, contact details, or any other relevant data for that user can be edited.

Note: Required meta-data fields are indicated in red. The window cannot be closed until all required fields are filled.

2. Double tap on a username to toggle activation and deactivation.
3. Tap the **Ok** icon . The changes are saved.

ICON KEY:

Check mark		User active
No check mark		User inactive (cannot login)
Locked out 		User locked out (cannot login)
Unlock 		Select username and tap unlock
Add 		Add user (Figure 9)

8.2. To Add a User

1. Tap the **Add** icon . The **Add User** screen (Figure 9) is displayed:

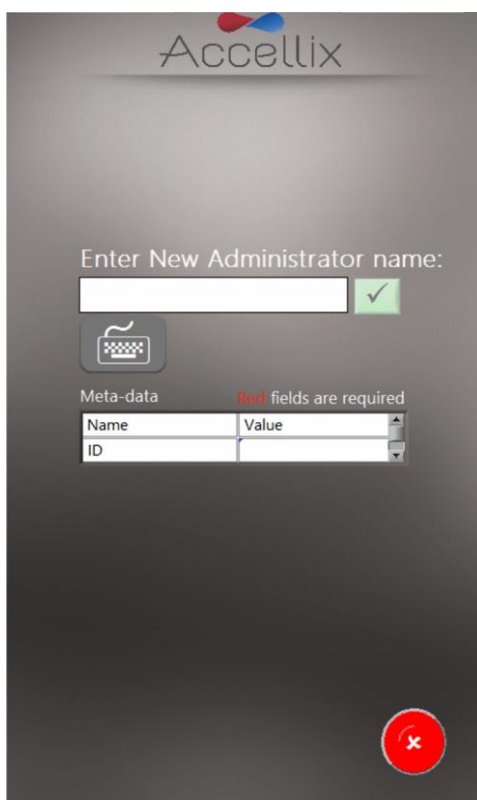



Figure 9: Add User screen

The **Ok** icon  only becomes active when a valid username is entered.

Note: A username cannot be blank or consist of only spaces, and it cannot contain any of the following characters: * \ / " : < > ? | _ % # & { } \$! ' @.

Note: The Meta-data fields will not appear if no Meta-data has been defined.

Note: If an **Operator** and **Administrator** have the same username, they are considered by the Accellix system to be the same person and the same meta-data will be used for both. The administrator with that username will not have the ability to deactivate a user bearing the same username.

2. Enter a new username and tap the **Ok** icon. The username is added to the list of users.

Note: All new users are required to change their passwords when logging in for the first time.

8.3. To Change Parameters

1. Tap **Parameters** at the top of the **Personnel** screen. All changeable login parameters (Figure 10) are displayed:

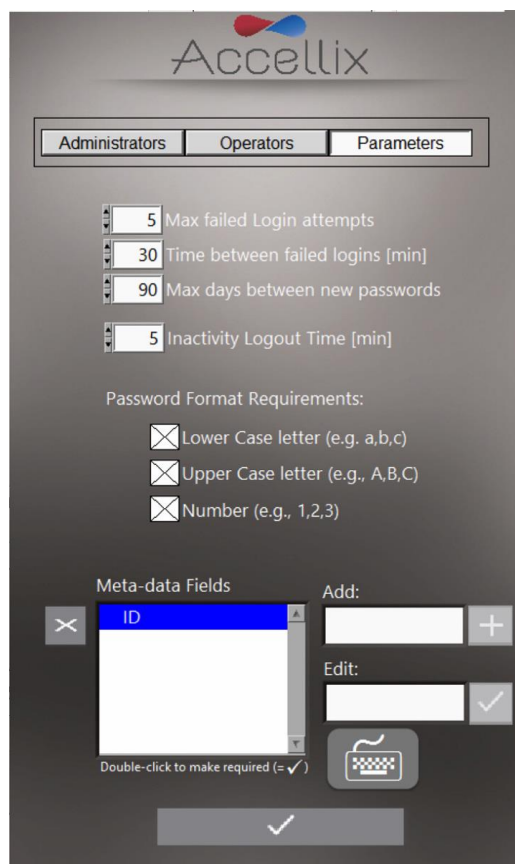



Figure 10: Login Parameter Options

2. Change parameters as required and tap the **Ok** icon . The changes are saved.
3. Meta-data fields displayed in Figure 10 are examples only.

The following parameters can be set:

Max failed log in attempts: Sets the maximum number of times a user can attempt to login before being locked out.


Time between failed log ins: Sets the number of minutes to wait before resetting “number of failed attempts” to zero if the “Max failed Login attempts” has not been reached. For example, if a user enters 2 incorrect passwords, and the “Time between failed log ins” is set to 30 minutes and “Max failed log in attempts” is set to 3 attempts, then after 30 minutes that user can try an additional 3 times as the “number of failed attempts” counter is reset to 0.

Max days between new passwords: Sets the number of days that elapse between the previous password change and when the user is required to change it again.

Inactivity log out time: Sets the amount of time (minutes) with no activity after which the user will be automatically logged out.

Password format requirements: Passwords must contain at least one character for each type selected.

Add (meta-data fields): Allows for adding a new meta-data field (type the name of the new field in the **Add** text box and tap the + button).

Edit (meta-data fields): Select a field name in the **Meta-Data Fields** list on the left. The name appears in the **Edit** text box on the right. Edit the field name and tap the **Ok** icon  to the right.


Double-click to make required (=v): Double-clicking on a meta-data field in the **Meta-Data Fields** list box will make it "required" and a checkmark (√) will appear to the left of that meta-data field.

Note: Double-clicking on a "required" meta-data field will make that field optional and there will be no checkmark next to it (√).

Delete: Use the Delete icon () to remove a Meta-data field

Note: Meta-data is intended to allow for additional, non-critical data about each user to be entered. For example, some possible meta-data fields are: "email", "Employee ID", and "Department". This data is generally "non-essential" but can be useful for certain organizations.

9. Changing Printer Settings

Tap on the **Settings** icon () to display the **Settings** screen (see Figure 11), which allows an administrator to select a specific destination printer and to change the auto-printing feature after an assay completes.

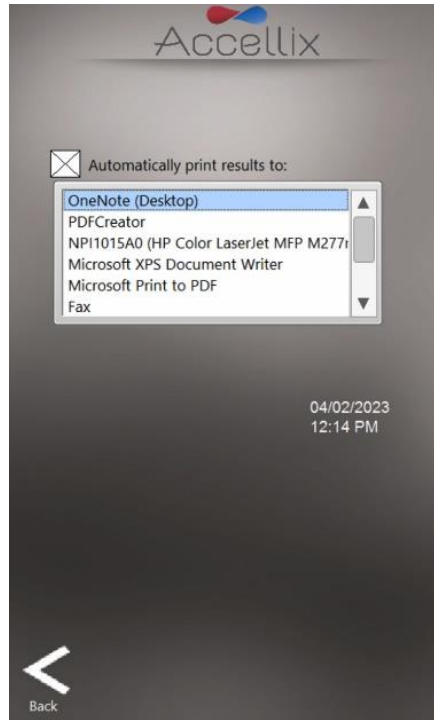


Figure 11: Changing Printer Settings

10. Viewing/Exporting the Audit Trail

10.1. To View the Audit Trail



Tapping on the **View Audit Trail** icon View Audit Trail displays the **Audit Trail** screen:



Figure 12: Audit Trail screen


The Audit Trail table is sorted by date and contains entries for the following columns per entry:

- **Date:** activity was recorded
- **Time:** activity was recorded
- **User Type:** Administrator or Operator
- **User:** name of the person performing the activity
- **Action:** recorded


The **Filter by:** dropdown box allows the table to be filtered by Username. Filtering by date has not yet been implemented. If the Audit Trail is filtered, the subset shown of the Audit Trail will be printed or exported.

Note: It is highly recommended to review the audit trail regularly as per local policy to ensure no data backup issues have occurred (See Section **15.2 Instrument Issues** for more information).

10.2. To Export the Audit Trail

1. Tap the **Export PDF**  icon. The table on the screen is exported to a PDF file.

OR

2. Tap the **Export Text**  icon. The table on the screen is exported to a standard tab-delimited text file.

The user is prompted to select a location and enter a name for the file (Figure 13):

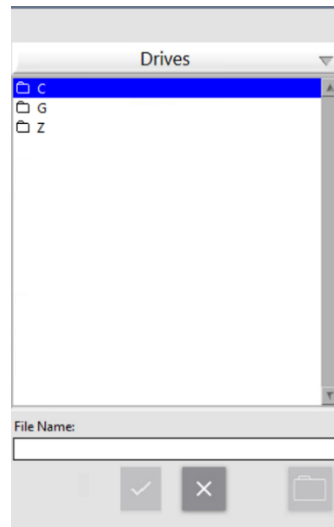



Figure 13: Save File dialog

3. Tap the **Printer**  icon to print the displayed table to the default printer.

11. Adjusting the Instrument Settings

Configure the instrument for use by adjusting the instrument settings according to the following steps:

1. Turn on the instrument by switching the **Power switch** on the rear panel of the instrument to the 'ON' position. While the instrument boots up, the display will inform the user that **System Self-check** is being performed (Figure 14):

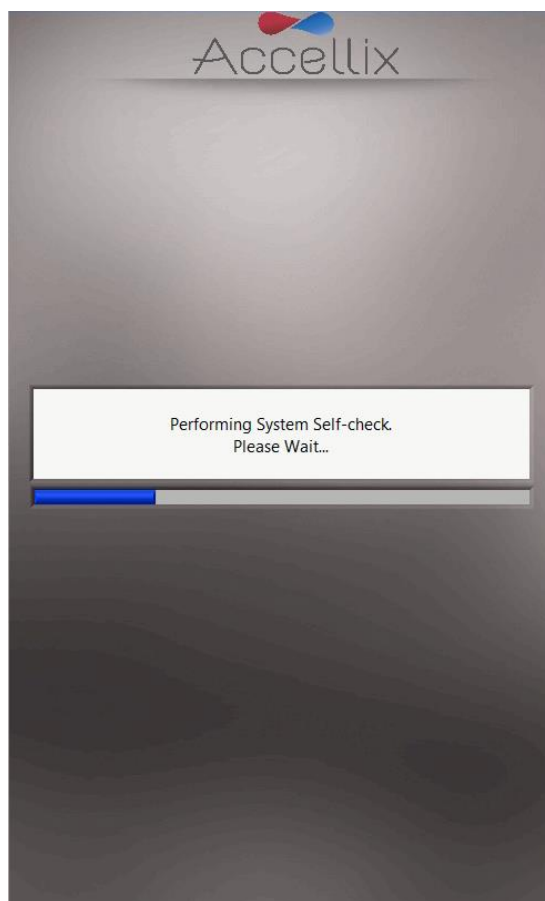



Figure 14: 'System Self-check' screen

2. Verify that system has successfully completed initialization, and that the **Home** screen (Figure 16), or the user login screen (Figure 5, if logins are enabled) appears on instrument display.

Note: Depending on instrument configuration, the **Settings** and **Administrator** icons may or may not be visible.

Note: If auto-classification subscriptions are enabled and an assay's subscription is due to expire within the next 6 weeks, the assay's name and expiration date will appear in **yellow** in a table above the blue Start button. If an assay's subscription has already expired, the assay name and expiration will appear in **red** (Figure 15).

Note: If the instrument has passed its Preventative Maintenance (PM) date, a warning will appear below the blue **Start** button (Figure 15).

Note: The free space available on the instrument's internal hard disk is displayed as a function of the total number of assays that can be run. Press the Refresh icon () located near the bottom of the display to refresh this number after manually deleting files (Figure 16).

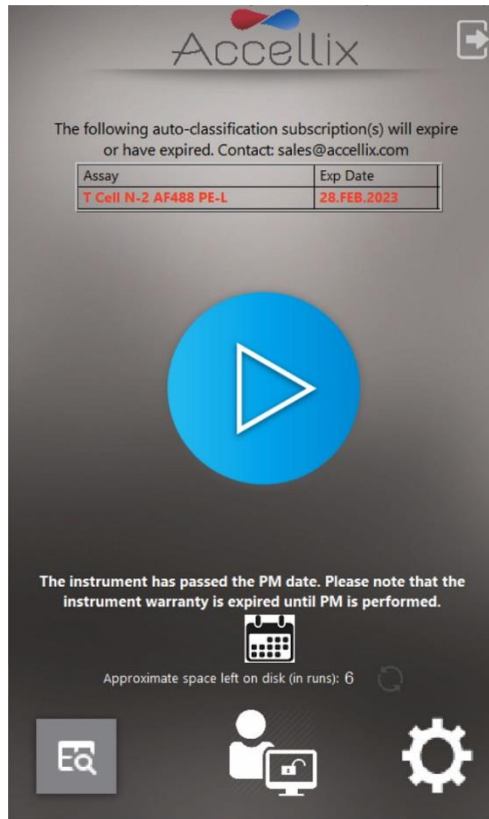


Figure 15: Home screen with login enabled, showing subscription status and PM status

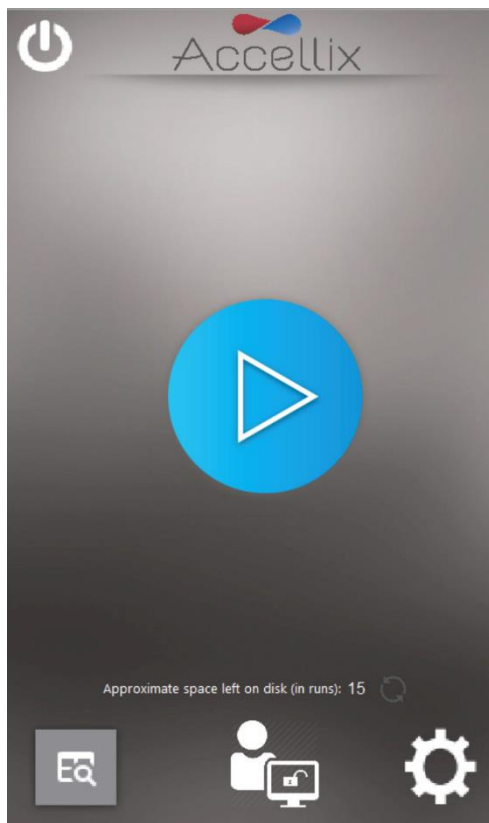



Figure 16: Home screen

3. Tap the **Settings**  icon at the bottom right of the **Home** screen to access the **Settings** screen (Figure 17).

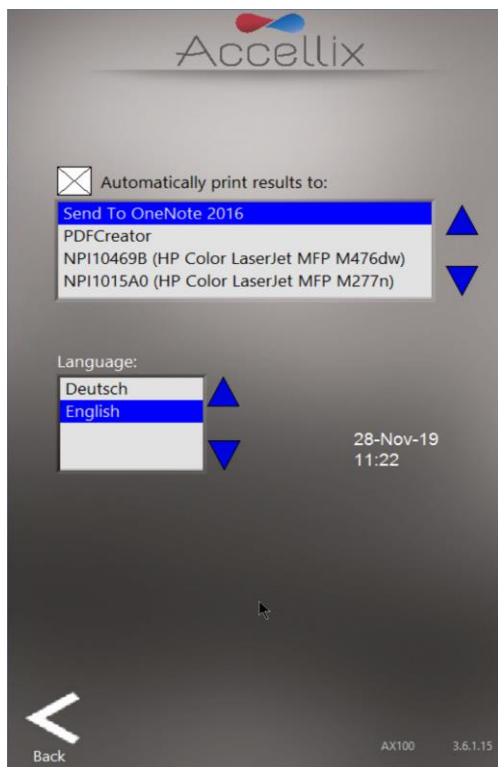



Figure 17: Settings screen

4. On the **Settings** screen, the user can check or configure instrument settings, as follows:


- **Printing Results:** If the checkbox is selected next to “**Automatically print results to:**” field, a printout will be sent to the printer which has been chosen from the list of available printers. If the checkbox is not selected, the results will not be printed automatically at the end of a test run. However, even if the automatic print function is not selected, the user can manually print the results from the **Results** screen once the test is completed.
- **Instrument Date/Time Display:** The date and time set on the instrument are viewable from this screen along with the name of the instrument and the current version of the software.

5. Tap the **Back** icon  to return to the **Home** screen. The Accellix instrument is now configured for use

12. Administrator Settings

Note: When Show admin functions is enabled for Operator users (configured during installation), Operators will also have the **Administrator** icon visible on the screen. If the Operator possesses the password, this user will also be able to access Administrator functions, which is a feature that doesn't support 21 CFR Part 11 compliance, and will be resolved in version 3.9.1, released in December 2023.

The instrument settings that can be defined or changed by an "Admin user" are accessed as follows:

1. Tap the **Administrator** icon  at the bottom center of the **Home** screen (Figure 16).
2. Enter the password in the **Admin User Password Window** (Figure 18) to access the **General Administrator Settings** screen (Figure 19).

Note: The password window will automatically close once the correct password has been entered.

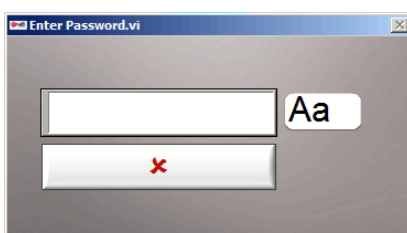


Figure 18: Admin User Password Window

Note: The user authorized to act as the instrument administrator should contact Accellix Support at support@accellix.com and provide the Instrument Serial number (located on the back of the instrument) to receive an Admin password

Note: If logins have been enabled and the user has logged in as an Administrator, no further password is required to reach the **General Administrator Settings** screen.

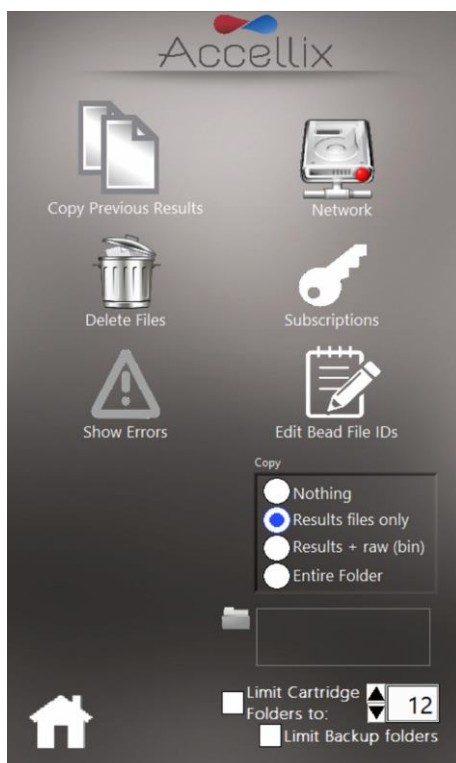


Figure 19: General Administrator Settings screen

3. On the **General Administrator Settings** screen, the user can enter or adjust the settings described in the following subsections.

12.1. Copy Previous Results Function



Using the **Copy Previous Results function**, Admin users can copy or move results files from past test runs by selecting a date range (Figure 20) and tapping **Copy Now**. Cartridge data folders created between the selected dates are displayed below the two calendars.

- If the **Results files only** radio button is selected, only the assay results and the associated .csv, .fcs, and PDF files are copied or moved:
 - If the **Include raw binary files** checkbox is selected, the software also copies or moves raw data files, as well as the .csv, .fcs and PDF files.
- If the **Entire folder** radio button is selected, the entire data folder (including .csv, .fcs, PDF, .bin, .png etc.; >1.7 GB) is copied or moved.
- If **Copy** is selected, the software only copies files based on the above selected options.
- If **Move** is selected, the software copies the files based on the above selected options and then deletes the original files once the file copy is successful.

The copy destination is selected in the **Destination Location** function, as explained below (See Section 12.7.2 - **Destination Location**).

The screen displays how much data will be deleted and how much space is currently available on the internal hard disk.

Note: When selecting the date range for copying results files, make sure to choose at least one day before and one day after the specific date range of interest.

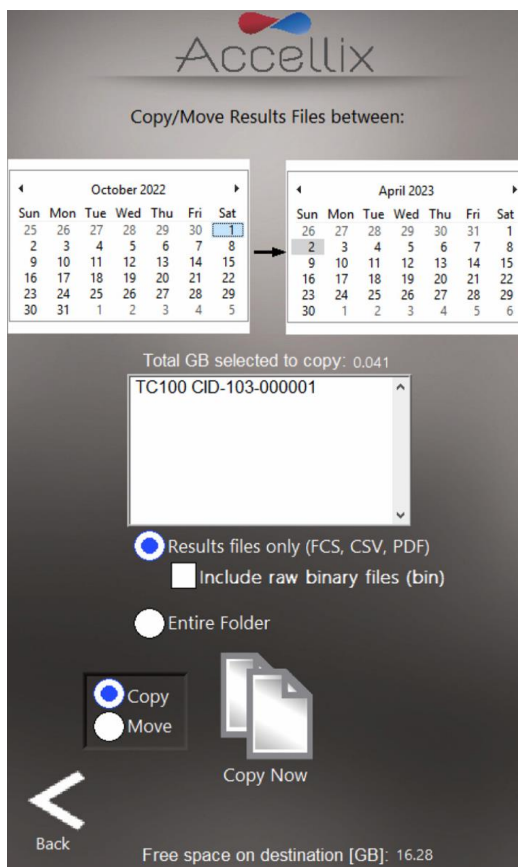


Figure 20: Copy/Move Results Files screen

12.2. Delete Raw Data Function



The admin user can the **Delete Raw Data Function** to free up space on the internal hard disk of the instrument.

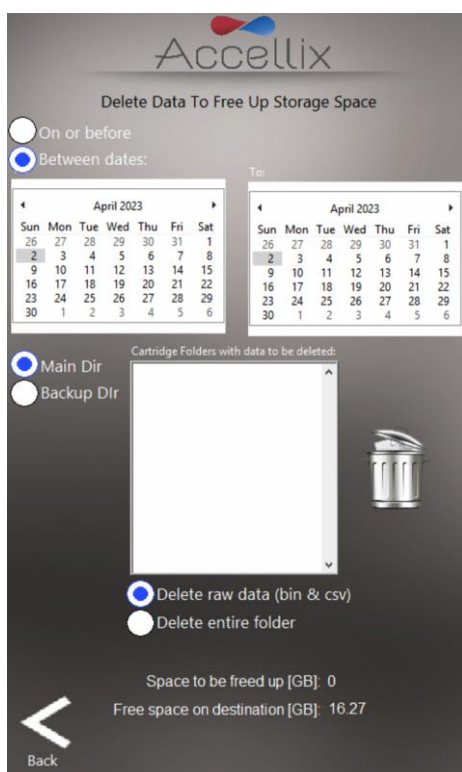
Files/folders can be deleted either on or before a specified date (“On or before”) or between a set of dates (“Between dates”).

Note: If data is backed up on the internal hard disk (C:\), =there is an option to delete files from either the main directory or the backup directory.



Tapping the Delete icon () deletes large raw data files created from each test run executed on or prior to the date selected in the date field (Figure 21).

- The window displays all folder names to be deleted in the list below the date.
- The space to be reclaimed and available is displayed in GB below the date.

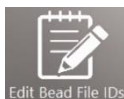


Note: The result output files, e.g. '.fcs' file, results report files, etc. for each test run on the instrument are always retained on the internal instrument memory; they will not be deleted when this function is used unless the Delete entire folder checkbox is checked.

Warning: Selecting the **Delete entire folder** checkbox and tapping on the **Delete** icon deletes all data folders displayed in the list. This action is **NOT** recoverable — data will be permanently deleted.

Figure 21: Delete Raw Data files screen

12.3. Edit Bead File IDs Function



The **Edit Bead File IDs function** window displays a list of all available bead lot files available for all assays that use these files (Figure 22). Currently, only the QC assay (QCB101) uses bead lots.

Note: Individual bead lots can be deleted if the original file needs to be replaced with a newer version.

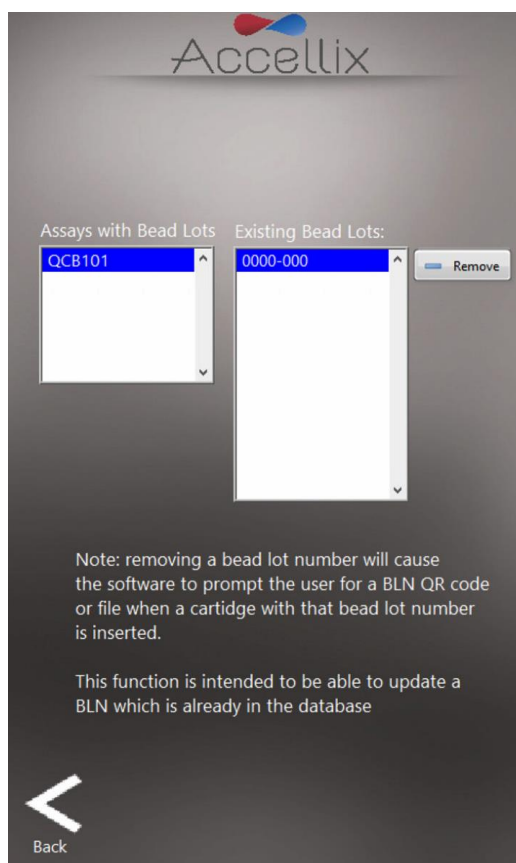



Figure 22: Bead Lot IDs screen

12.4. Runs with Error Function



The **Runs with Errors function** has two functions:

1. If **View Runs with Errors** is selected, files related to test runs for which errors were generated can be selected and copied (Figure 23). Individual cartridge data folders can be selected together by holding down the Control Key on an attached keyboard while tapping an entry in the list. Tap the **Copy** Icon.
 - The amount of hard disk space required to copy these files is displayed (“**GB to be copied**”), along with the space available on the destination drive (“**GB Available**”).
 - The copy destination is selected in the **Destination Location** function (Figure 31).
2. If **View Log File** is selected, the Log File Entries are displayed (Figure 24). Tap the printer icon  to print the log file.

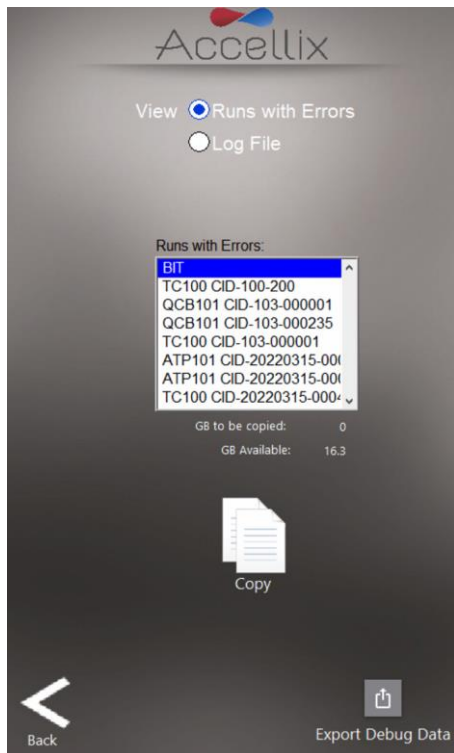


Figure 23: Copy Test Runs with Errors screen

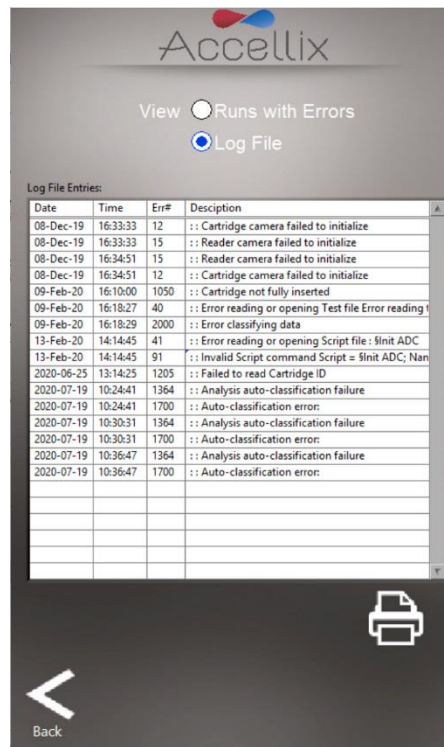


Figure 24: View Log File screen

Note: Pressing the **Export Debug Data** icon  will export a compressed (zip) debug data file to a specified location. Only use this button if instructed to do so by Accellix personnel.

12.5. Network Function




The **Network function** screen (Figure 25), has 4 tabs: Map Drives, IP Config, WiFi, and LIMS.

1. The Map Drives tab (Figure 25) allows the user to map a drive letter to a network drive.

a. **To map a drive:**

- Select a drive letter
- Enter the network address
- Enter the username
- Enter the password
- Click on “Save & Map”

Note: To view the password in clear text and hide it again, use the **View Password** button ()

b. **To unmap a mapped drive:**

- Select the drive to unmap
- Click on the “Unmap” button



Figure 25: Network Screen: Map Drives tab

Note: When mapping a drive as a backup location, don't forget to set the backup location to that drive.

2. The IP Config tab (Figure 26) allows the TCP/IP address for either of the Accellix instruments' two Ethernet ports to be configured dynamically or with a static IP address. To set a static IP:
 - Select the desired port from the drop-down menu
 - Select **Use the following IP address** radio button
 - Fill in the IP address, Subnet mask, and Default Gateway
 - Click on the checkmark icon ()

Note: If any errors arise, they will be displayed below the Default Gateway.

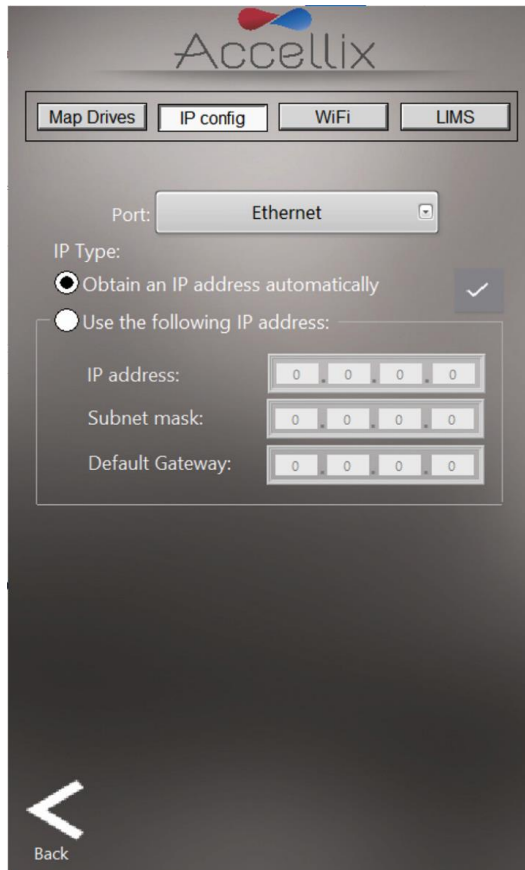







Figure 26: Network Screen: IP Config tab

3. The WiFi tab (Figure 27) used to connect to a WiFi network. To connect:
 - Select a WiFi Network from the drop-down menu
 - Enter the password
 - Click on the Login button ()

Note: A red X () indicates that the network is not connected.

Note: A green checkmark () indicates the network is connected

- To log out, click on the Logout button ()
- The Refresh button () will refresh the list of available WiFi networks

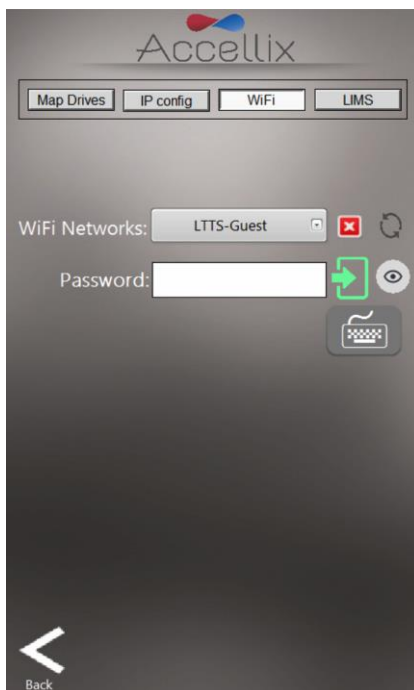


Figure 27: Network Screen: Wi-Fi tab

4. To configure a system to save data to the LIMS system, select the LIMS tab (Figure 28) to enable the system to save data to the LIMS system:
 - Click on the LIMS button at the top of the screen
 - Select the “Save results to LIMS” checkbox
 - Select the “Print after saving to LIMS” checkbox as an option, if desired
 - Enter the LIMS address

Note: If any errors arise, they will be displayed below the LIMS address field.

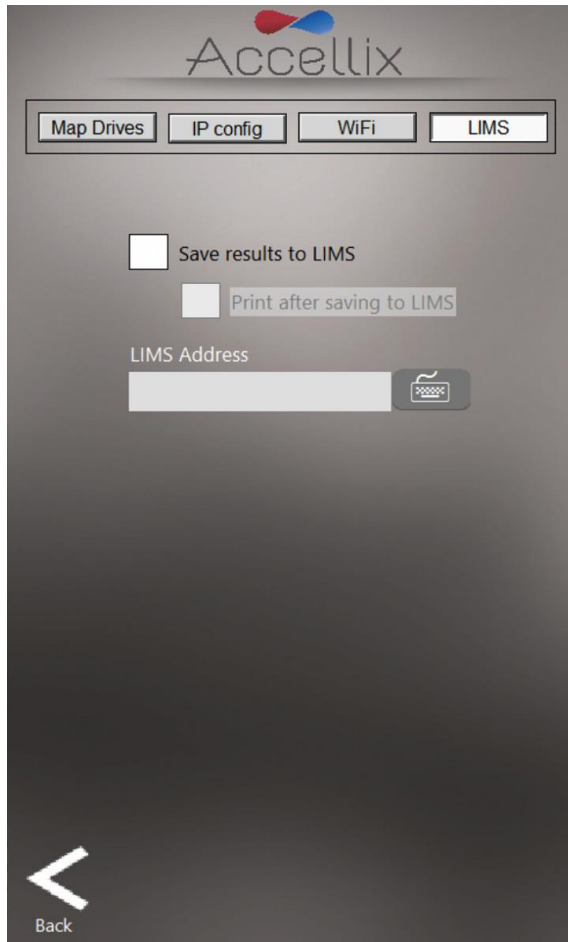



Figure 28: Network Screen: LIMS tab

12.6. Auto-Classification Subscriptions Function



The **Auto-Classification Subscriptions function**  screen allows the user to view and add auto-classification (AC) subscriptions for any assays with AC subscriptions (Figure 29).

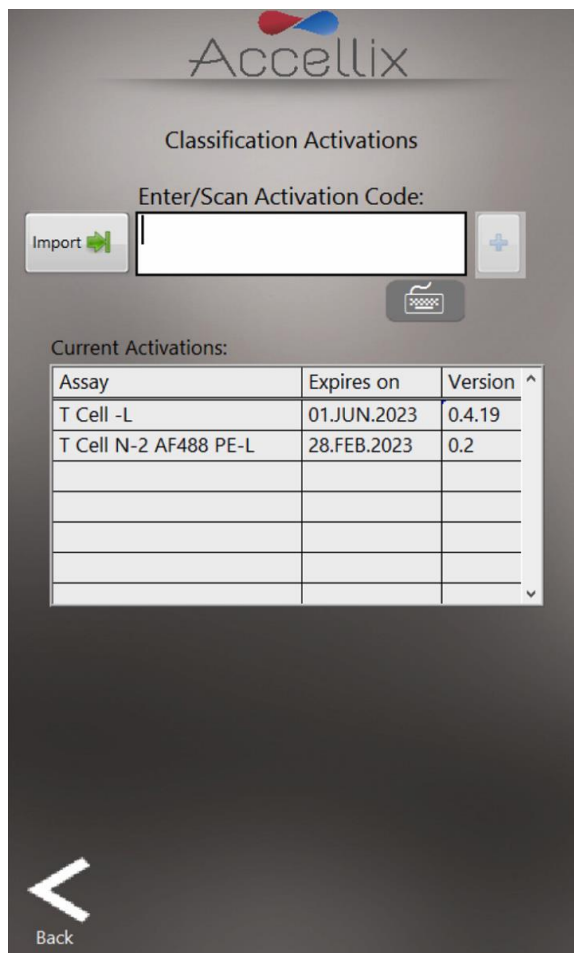



Figure 29: Auto-classification Subscriptions screen


The table displays all the subscriptions currently installed with the assay name, the date it has or will expire, and the version number.

To add a subscription, click on the **Import** button () and navigate to the subscription file sent by Accellix in the resulting file dialog window. Selecting the file will either add the assay to the list (if it is not already present) or update its expiration date (if it already exists in the list).


Note: It is possible to type a code manually, but it is important to note that the codes are long and case sensitive.

12.7. Copy Function & Destination Location

12.7.1. Copy Function

Copy function : This setting determines what results should be copied to the destination location at the conclusion of an assay run.

12.7.2. Destination Location

Destination Location: The destination where the results should be copied is displayed in the field directly below the Copy options. Set the path by using the folder icon  next to the destination location field (see red box in Figure 30).

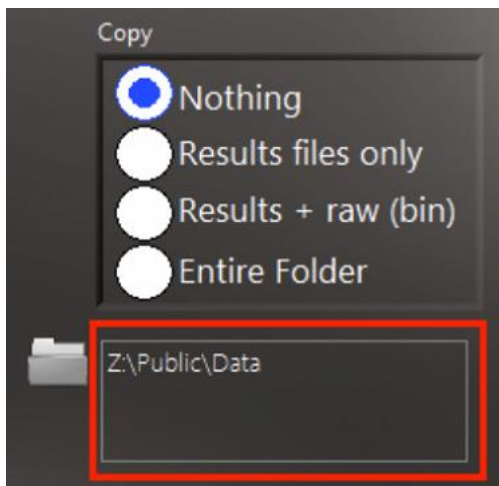


Figure 30: Copy and Destination Location section

Tapping the folder icon displays the **Set Data Destination Configuration** screen (Figure 31):

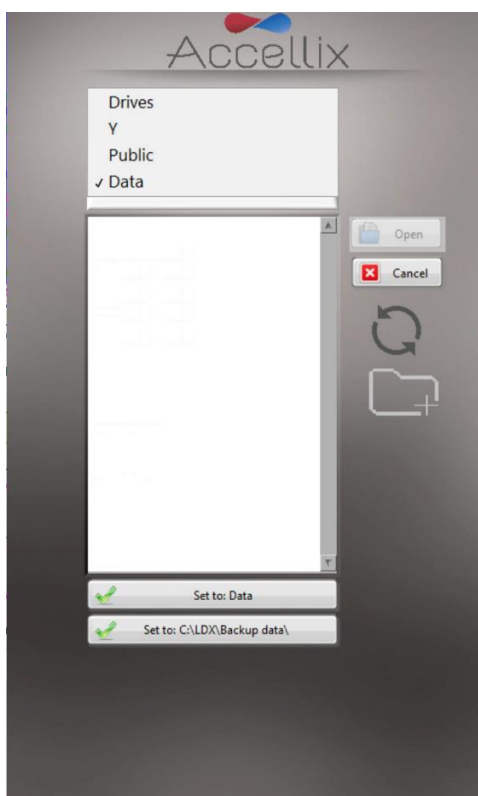






Figure 31: Set Data Destination Configuration screen

- The pop-up menu allows the user to navigate up the folder structure hierarchy where the current folder selected is located at the bottom. To select the relevant path, select the specific location by double clicking on it or using the “Open” button and then tap the “Set to” button, which contains the name of the final data folder.

- The contents of the currently selected folder are displayed in the list box below the pop-up menu. By selecting **Drives** in the pop-up menu, a list of all available drives is displayed in the list box.
- If the software is configured to allow saving to a specific folder on the internal hard disk (C:\) a button appears below the “Set to” button, which allows the user to set the backup location to the specific location (as configured in the software’s configuration file).

ICON KEY:

-  Saves the current folder as the destination folder for all data to be copied
-  Cancels any changes and leaves the destination location the same as it was before entering this screen
-  Rescans the currently selected folder and updates the list of contents
-  Allows the user to create a new folder within the current folder

12.8. Limited Cartridge Folders Function

All files, including raw data files, results reports, etc., generated by the instrument for any test run are automatically stored in the instrument’s internal hard disk. This location is not accessible by users but can be accessed upon request by Accellix Support.

Note: The raw data (.bin) files are each approximately 1.25 GB. When the **Limit Cartridge Folders to** checkbox is selected (Figure 32), the software retains only the newest *N* folders (where *N* is the number typed in the field next to **Limit Cartridge Folders to**). All older cartridge data folders are deleted.

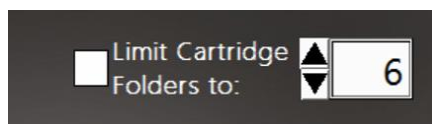


Figure 32: Limit Cartridge Data Folders controls

Note: If the instrument is configured to back up the data to a location on the internal hard disk (C:\), a second option appears, allowing data stored in the backup folder to also be limited (Figure 33).

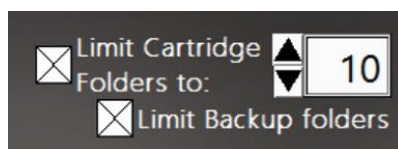


Figure 33: Limit Cartridge Data & Backup Folders controls

13. Operating the Accellix Platform

To ensure the successful operation of the Accellix Platform, a user is expected to undergo basic training procedures. This training includes instructions on operating the instrument (as outlined in the Accellix User Manual and Instructions For Use), safety procedures, troubleshooting techniques, and guidelines on when to contact the manufacturer for service. This training should be performed by an Accellix Field Applications Scientist, or by an experienced user who has previously undergone training with an Accellix Field Applications Scientist.

The Accellix platform performs flow cytometric reading of an assay sample according to test parameters defined in the technical data sheet of the relevant assay.

13.1. To Run an Assay on the Accellix Instrument:

1. If logins are enabled, select an Operator and log in (the **Home** screen will appear).
2. Follow the Accellix Assay “Instructions for Use” and add the cell sample to the cartridge according to the relevant protocol for the cartridge type. (Find the Technical Data Sheet and Instructions for Use for details and instructions for each Accellix assay type or <https://www.accellix.com/technical-resources/>)

Note: After the sample plug/seal is closed, the assay should be initiated immediately.

3. Run an assay as follows:

On the **Home** screen display, tap the **Start** icon  and follow the instructions displayed on the instrument’s screen.

Note: From this point forward, the highlighted gray dot at the bottom of the screen shows the current stage of the assay run.

4. When prompted by the instrument (Figure 34), open the door by pressing down on the front right-hand indent corner of the door and releasing. Next, insert the cartridge into the instrument by pushing it down using the top handle. Once the cartridge is inserted, push the handle on the right-hand side a bit more until a click is heard and felt, ensuring that the cartridge has been inserted fully into the instrument Cartridge Handling Unit (CHU).

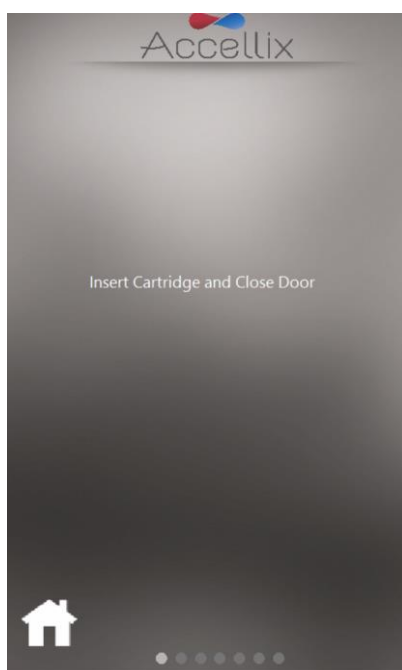


Figure 34: Insert Cartridge screen

5. The screen instructs the user to wait while the instrument reads and registers the QR code information on the cartridge (Figure 35).

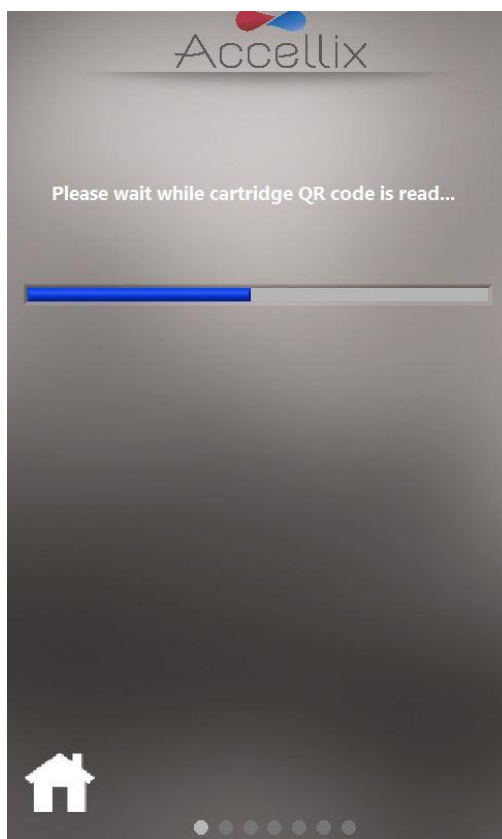


Figure 35: Reading Cartridge QR Code screen

6. On the **Enter Sample ID screen** (Figure 36), enter the Sample ID using the on-screen keypad by using an external keyboard or barcode scanner. The Sample ID will then be displayed on all subsequent screens of the assay run.

Note: To proceed, at least one character must be entered as the Sample ID. It should not be any of the following characters or only spaces: * \ / " : < > ? | _ % # & { } \$! ' @.

Note: In an optional configuration of the software, the user is also required to enter a Kit Number.

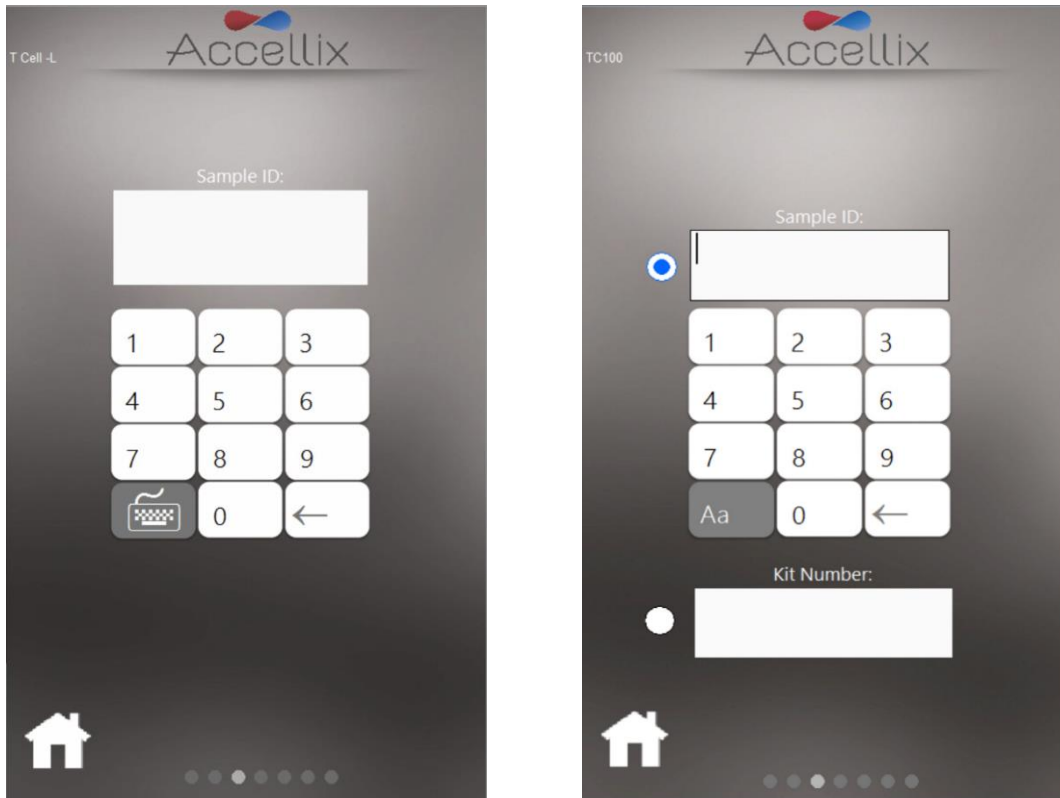



Figure 36: Enter Sample ID screen (with and without Kit Number)

7. Once the Sample ID (and Kit number if applicable) field is no longer empty, the Next  icon will appear.
8. Tap **Next** to continue.
9. The **Confirmation screen** (Figure 37) now displays the assay/cartridge type and Sample ID (and kit number if so configured). The user must confirm these details before starting the assay run by tapping **Next**.

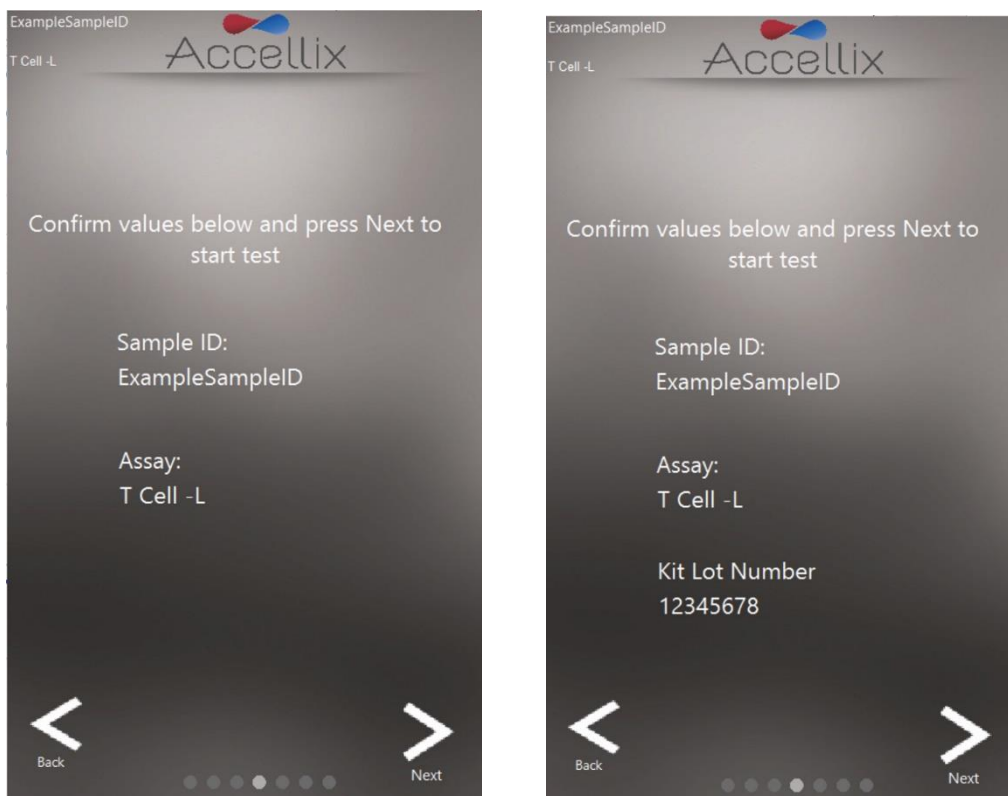
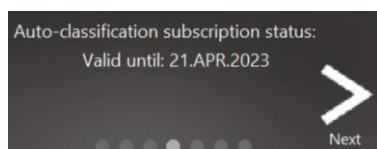


Figure 37: Confirm Sample ID and Assay/Cartridge screen (with and without Kit Number)

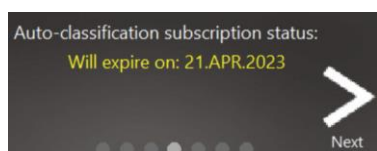
Note: Tapping on the **Back** icon will return the user to the Sample ID screen. This is useful if incorrect information was entered, or the run needs to be stopped for any reason.

Note: If the selected assay requires an auto-classification subscription and doesn't have one, a message will be displayed at the bottom of the Confirmation screen.

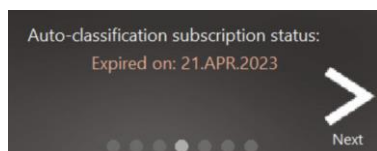
If the assay chosen to run requires an auto-classification subscription, any one of the 4 following messages can appear at the bottom of the **Confirmation screen** depending on the status:



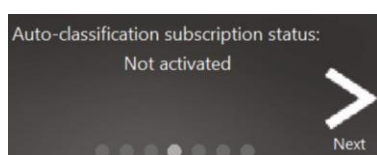
This will appear if the auto-classification subscription is valid and is not due to expire within the next 6 weeks



This will appear if the auto-classification subscription is valid but is due to expire within the next 6 weeks



This will appear if the auto-classification subscription has expired. In this case, only Total Bead Count will be displayed.



This will appear if no auto-classification license has ever been applied for this device. In this case, only Total Bead Count will be displayed.

10. After tapping **Next**, the test proceeds in accordance with the specific parameters relevant to selected assay/cartridge type.

Note: Once the **Next** button is pressed on this screen a cartridge is considered used and cannot be reused.

11. The **Progress screen** (Figure 38) displays a progress indicator and a **Time Remaining** countdown timer. The user can monitor the test progress and approximate time remaining.

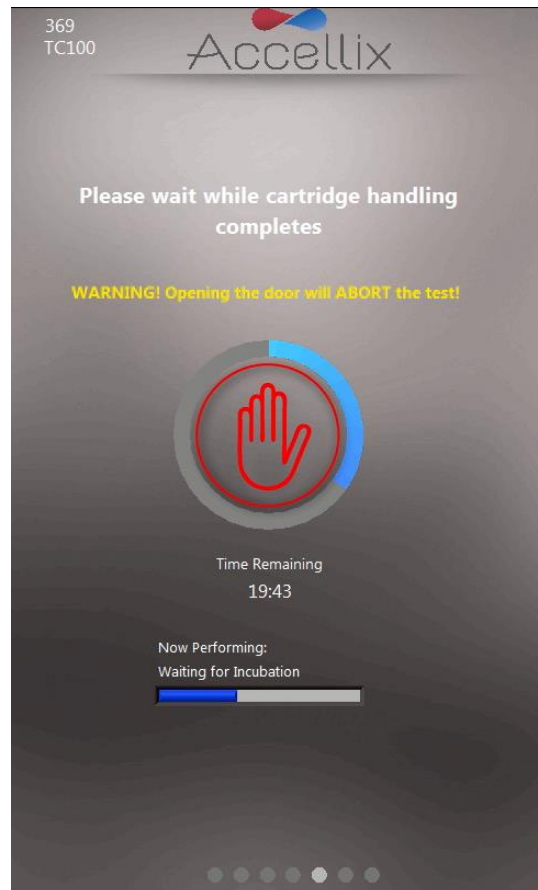


Figure 38: 'Progress Indicator and Time Remaining' screen



Aborting a Running Assay: Exercise caution to avoid opening the instrument door while an assay is in progress, as this will cause the assay to abort. In addition, do not attempt to remove the cartridge while an assay is running on the instrument. A cartridge should only be removed from the instrument once the “Open door and remove cartridge” message appears on the screen.

Note: To stop an assay that is in progress, the user can tap **Stop**, the red hand at the center of the progress indicator (see Figure 38). Refer to Section **13.3 Termination of an Assay Run**.

Note: When aborting an assay, confirmation is required from the user to proceed with the abort and a dialog box will appear, requesting the user to add “Reason Aborted.” If so configured, a comment may be mandatory.

Note: If a physical keyboard is not attached to the instrument, a virtual keyboard can be displayed by tapping on the keyboard icon.

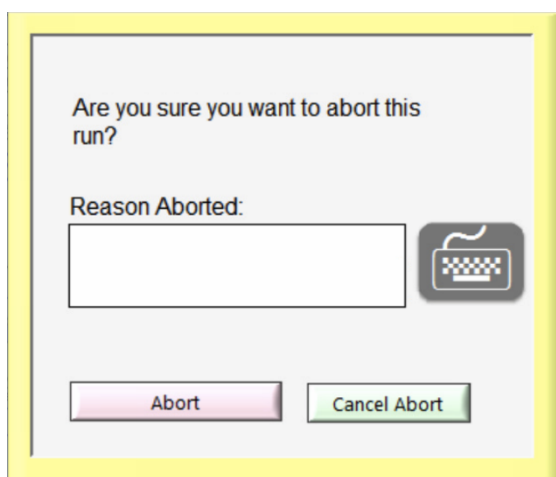


Figure 39: Confirm Abort Dialog

12. Upon completion of the assay, the results are copied to the designated backup location. The instrument notifies the user by displaying one of four possible results screens, depending on the assay configuration: No Results, Pass/Fail, Total Bead Count only or an on-screen table with all results.

The following two screens are examples of potential result displays (Figure 40 and Figure 41):

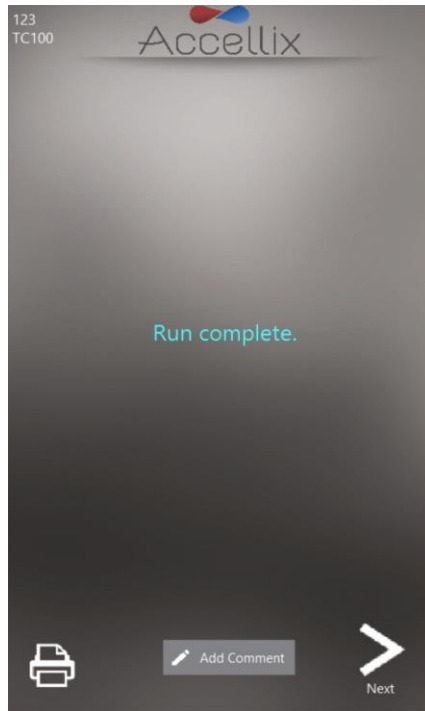


Figure 40: Example of Run Complete screen

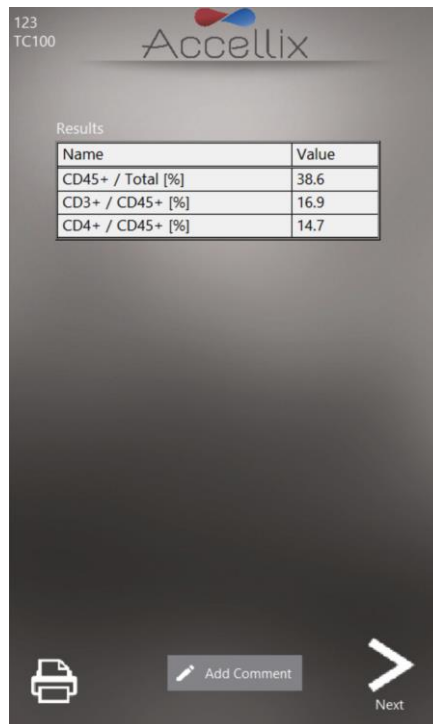



Figure 41: Example of On-screen Results Report

- a. For an assay which produces an on-screen results report, e.g., T Cell RTF (L) Assay, a **Results** screen will be displayed on the screen at this point. See example of on-screen **Results** report in Figure 41.
- b. For an assay which generates a **Results** output, a printable report will also be generated. The report will be printed automatically at this stage if this was configured in the **Settings** screen, prior to initiating the assay.
 - If automatic printout was not configured or if the user chooses to print to an alternate printer, a manual printout can now be initiated by tapping on the **Printer**  icon at the bottom-left of the **Results** screen. The user may select desired printer from the **Printers** list, and then tap **Printer** icon to execute the manual printout.

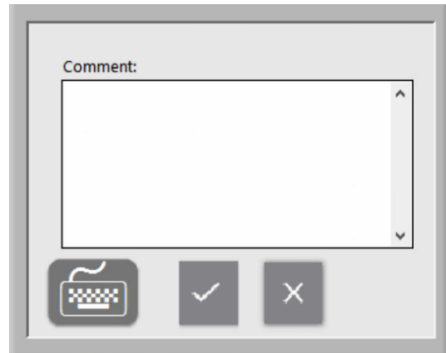


Figure 42: Comment Window

- If desired, a comment can be added to the Assay Results.pdf by tapping on the **Add Comment** button. This will open a Comments window where the user can add a comment (Figure 42).

Note: A new PDF called “Assay Results with Comment.pdf” is generated if a comment is added. This PDF will be copied to the backup location once the Next button is tapped on the Results screen.

Note: A virtual keyboard can be displayed by tapping on the keyboard icon if a physical keyboard is not attached to the instrument.

13. Tap the **Next** icon when ready to conclude the assay process.
14. On-screen instructions (Figure 43) prompt the user to open the instrument door, remove the cartridge, and finally to close the instrument door.

Note: It is important that the instrument door remains closed between assay runs to prevent foreign particles from entering the instrument interior.

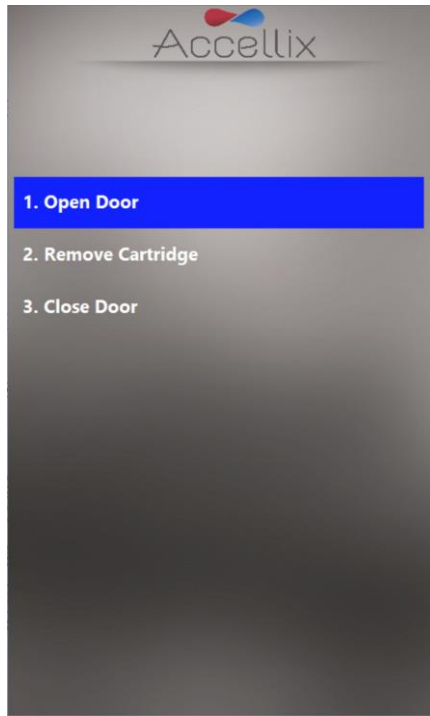


Figure 43: Remove Cartridge screen displayed following conclusion of test

15. The software returns to the **Home** screen.
16. The cartridge should now be disposed of in a suitable biohazard waste receptacle in accordance with organizational policy and/or local regulations.

13.2. To Run a Multi-cartridge Assay

1. The **Multi-cartridge Remove Cartridge** screen instructs the user to remove the first cartridge and insert the next cartridge in the sequence (Figure 44).

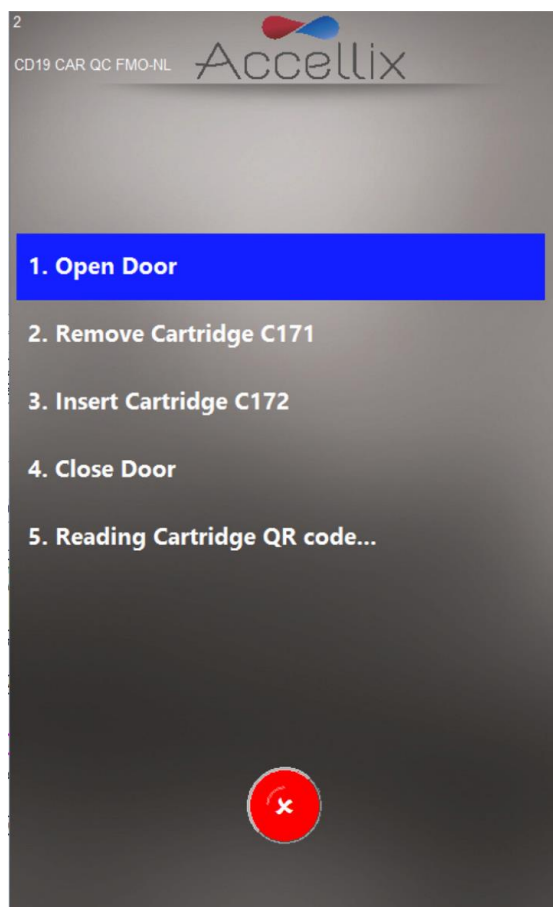


Figure 44: Multi-cartridge Remove Cartridge screen

2. If the user inserts the incorrect type of cartridge, the user is instructed to remove the incorrect cartridge and replace it with the correct type. The software scans the QR code upon insertion of the next cartridge to verify if it is the correct type to run next.

Note: The user may abort the programmed continuation with the next cartridge by tapping the red



Abort icon.

3. Once the correct next cartridge of a multi-cartridge assay has been inserted, the software will display the **Confirm Sample ID and Assay/Cartridge** screen (Figure 37) and continue with that cartridge.

13.3. Termination of an Assay Run

The **Abort** icon may be used to terminate an assay run (Figure 38).

If an assay is stopped during the run, a message will be displayed on the screen (Figure 45). During this time, the system returns the cartridge to home position. It is important to note that the homing of cartridge may take some time, as the test scripts must be aborted, and internal motors move back to their home positions. Please be patient while the system completes this operation.

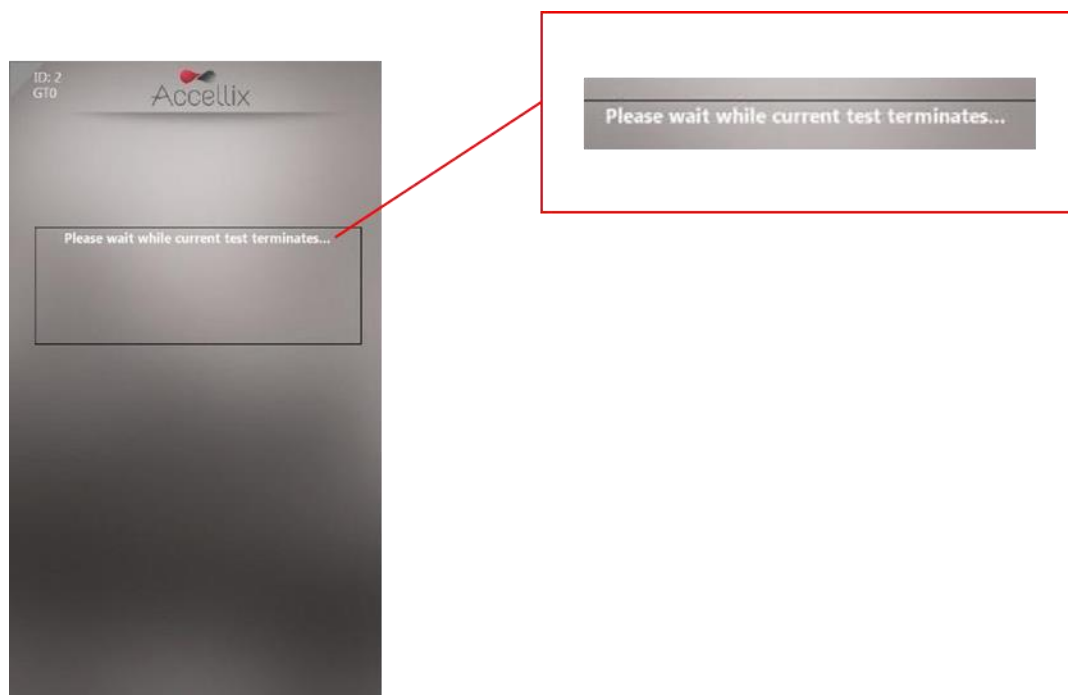



Figure 45: On-screen message following termination of assay run

Note: The cartridge should only be removed from the instrument after the user receives the prompt on the display panel.

14. Shutting Down the Instrument

The instrument can be left powered on, and there is no need to shut it down regularly.

14.1. To Shut Down the Instrument

1. On the **Home** screen (if logins are not disabled) or on the Login screen (if logins are enabled), tap the **Shutdown** Icon .

The user is prompted to confirm the shutdown (Figure 46).

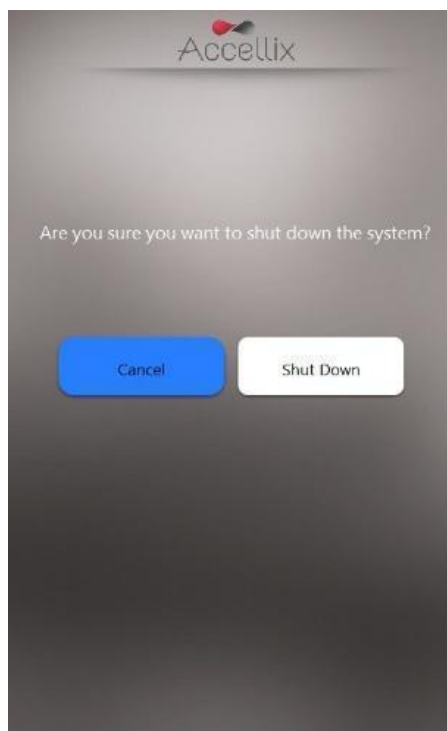


Figure 46: Confirm Shut Down screen

2. Shutting down the instrument is a 2-step process:
 - a. Tap the **Shutdown** icon to start the power down sequence.
 - b. Once the instrument's screen is black it is safe to turn off the physical power switch on the rear panel of the instrument. Shutdown is completed only after the power switch on the rear panel of the instrument is off.

To turn the instrument back on, move the **Power** switch on the rear panel of the instrument to the **ON** position.

15. Troubleshooting

There are two basic types of unexpected issues which can arise when using the Accellix instrument:

- issues related to a cartridge
- issues related to the instrument

15.1. Cartridge Issues

The following scenarios may invalidate a cartridge run:

- The system does not recognize the cartridge QR code
- The cartridge is past its expiration date
- Analysis of the sample fails
- Run aborted due to door opened during run
- Tampering with the Accellix assay components
- Not following recommended Accellix Instructions For Use

Specific instructions for each error type are provided on-screen (Figure 47).

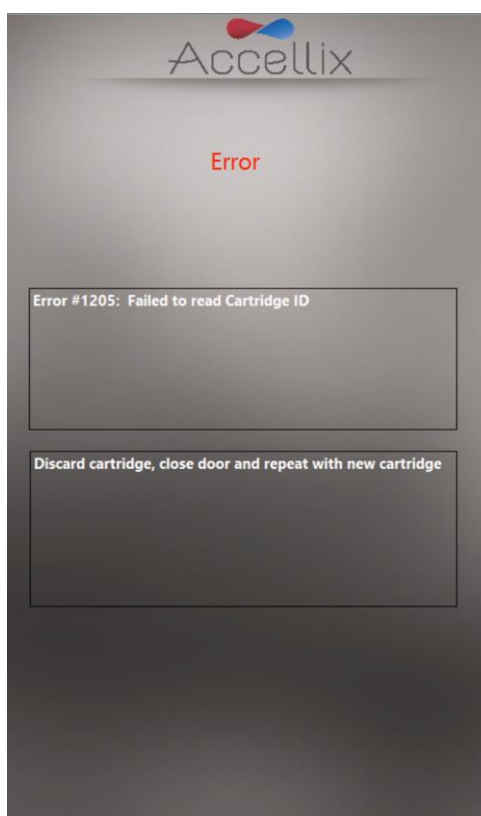


Figure 47: Example of Error Message

In all such cases the cartridge should be removed, and the door closed to return to the **Home** screen.

15.2. Instrument Issues

With the exception of **Hard Disk Full** warning and **Network Errors** (see below), recovery from all other anomalous behavior of the instrument can be performed by tapping the **System Self-Check** icon



or by turning the instrument off and then back on. If the System Self-Check/Restart does not resolve the issue, please contact Accellix Support to report the error. For further information on how to report the error to Accellix Support, refer to **Appendix E – User Support & Manufacturer Contact Information**. Upon completion of a successful System Self-Check, the system returns to the **Home** screen to allow the user to run another test.

Hard Disk Full warning:

In general, most hardware-related instrument issues can be resolved except when the instrument's hard disk becomes full. The Accellix Instrument stores data files generated for each assay on its internal hard disk, which can reach capacity over time as more assay runs are executed. The instrument checks to make sure that there is at least enough hard disk space to successfully complete an assay run first prior to executing an assay run. If the **Hard Disk Full** warning (Figure 48) is displayed, hard disk space must be freed prior to initiating a new assay run.

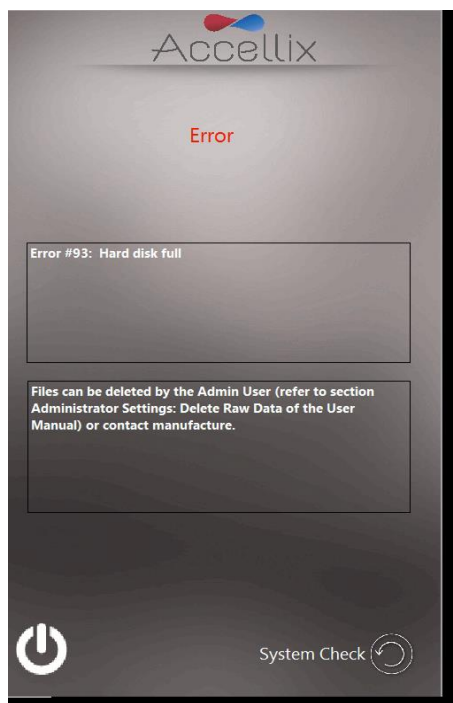



Figure 48: Hard Disk Full warning screen

Hard disk space can be freed by the Admin user using the **Delete Raw Data**  function (See **Administrator Settings**) or by using the **Move** option from the **Copy Files** function (Figure 20). Contact Accellix Support for further assistance.

Touchscreen Issues:

If the touchscreen does not respond, the user can connect an external mouse and keyboard, as well as a barcode scanner as described in Section 5.2 **Installation of Computer Hardware**.

Network Errors:

If a network outage occurs during the data backup process, the instrument will make up to three attempts to complete the backup. However, if the backup fails after multiple retries, this will be logged in the audit trail for reference. It is highly recommended to review the audit trail for such

errors regularly to ensure relevant data is manually backed up to the remote data location. Failure to do so may result in data deletion if auto-delete is configured or manually executed on the instrument.

Other Issues:

In rare instances, inaccurate results may occur due to incorrect usage of the instrument. The instrument should be used in strict accordance with this User Manual. Contact Accellix Support if the system does not start, if instrument performance issues are suspected, or for further troubleshooting assistance.

16. Handling Instructions

Handle the instrument with care. Once installed, the instrument should not be moved. If the instrument requires moving after installation, contact Accellix Support.

Protect the system from direct sunlight, humidity, and dust.

Operate only at permitted environmental operating conditions, as follows:

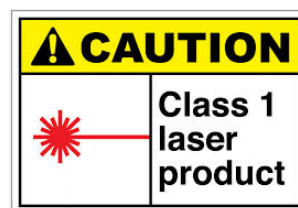
- Operating Temperature: 20-25°C (68-77°F)
- Max. Rel. Humidity 85%, Non-condensing

For information on instrument dimensions and power, refer to **Appendix A – Technical Specifications**.

17. Maintenance

Annual maintenance of the instrument is recommended. For safety and best results, take note of the following:

- **On-screen Instructions:** The user should follow the instructions as indicated by the error messages. (See Section 15 Troubleshooting)
- **Laser Safety note:** This instrument is classified as a Class 1 Laser product, according to IEC-60825-1 edition 3. Internally, the instrument uses a 50mW, 488nm Class 3B laser. The user/technician should never open the laser.



- **Network Connectivity:** To connect the instrument to a local area network (LAN), Wi-Fi network, or to a network printer, seek assistance from qualified IT personnel. (Connection to a user LAN should be performed using a cable that is less than 3 meters in length.)
- **Cleaning the System:** Accellix instrument may require cleaning periodically. To maintain the integrity of all Accellix components, perform cleaning according to the following procedure: Wipe the affected instrument surface with any of the materials listed in the next paragraph. Follow the directions provided with the cleaning product.
- **Decontamination:** If a cartridge is damaged after being inserted into the instrument, biohazardous material may leak into the instrument. In such a case, wipe down the front, sides, top, and bottom of the instrument with Pursept® disinfecting wipes, Medipal 3in1® Disinfectant Wipes, or other similar ethanol-based wipe. To thoroughly clean the CHU opening, a wipe wrapped around a long Q-tip can be used. All blood products should be treated as if they may contain pathogens.
- **Disposal Procedure:** The instrument should be disposed of according to local regulations regarding electronics and medical equipment waste. Dispose of used cartridges as a biohazard in accordance with local regulations.
- **Service Manual:** Servicing should not be performed by the user. All servicing must be performed by an Accellix Field Application Scientist according to manufacturing and re-work procedures.
For servicing, see Customer Support contact information at the end of this document, and/or see manufacturer website at www.accellix.com.
- **Shipment for Service:** To arrange a shipment for service, contact the manufacturer for further instructions. In case shipment for service is required, contact the manufacturer. Customized shipping container and materials, and a packing/shipping procedure will be sent to allow for secure shipment of instrument. If the instrument has been used with biohazardous samples, it should be enclosed in the provided biohazard bag before being placed inside the shipping container.
- **Calibration:** The instrument automatically performs a self-check to test and verify its functionality. If calibration is required for a certain cartridge or assay type, the Technical Data Sheet associated with each assay kit provides detailed information regarding the nature and frequency of calibration needed to ensure that the instrument operates properly and safely.

18. Assay-Specific Information

Assay-specific information is provided in the Technical Data Sheet and Instructions for Use for that specific assay which is included with each shipment of assay kits.

Appendix A – Technical Specifications







INSTRUMENT DESCRIPTION	SPECIFICATION
Instrument Dimensions	37 x 23 x 51 cm; 13.5 kg
Electrical Requirements	100-230V AC, 50/60Hz; Power draw: steady-state 35W, peak 90W
Replaceable Fuse	250V, 3A
Operating environment	Operating Temperature: 20-25°C (68-77°F) (max. rel. humidity: 85%, non-condensing) System should be protected from exposure to direct sunlight, humidity, & dust Instrument should have clearance of at least 20cm (8 inches) from both sides
Excitation Laser	488nm, cyan (40-50mW)
Fluorescence Detector	High-performance SiPM (silicon photomultiplier) array (11 channels)

INSTRUMENT DESCRIPTION	SPECIFICATION
Fluorescence Detection Range	510–800 nm
Forward Scatter Detection	Si PD (silicon photodiode); Collection angle: 6-11deg
Focus and Alignment of Optical platform	Real-time focus and excitation alignment, utilizing proprietary image analysis control algorithm
DAQ A/D Resolution, Sampling Rate	16-bit, 100kHz
Software	Accellix custom software, running on embedded PC; Operating System is Windows 10® Enterprise 2016 LTSB (64-bit)
Test Run Automation	Via control of instrument motors that provide functionalities including the following: <ul style="list-style-type: none"> • Auto-focus • Auto-alignment • Reagent injection/fluid release from cartridge blisters (x3) • Sample mixing • Sample reading

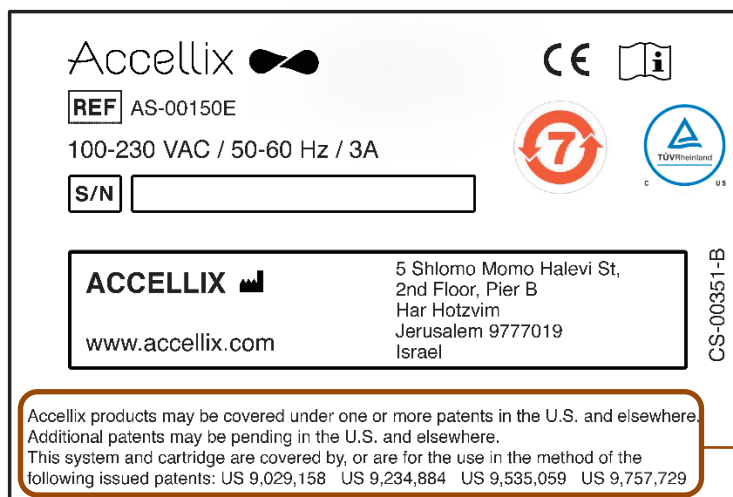
CARTRIDGE DESCRIPTION	SPECIFICATION
Cartridge Dimensions	7.9 x 8.5 x 1.2cm
Performance Characteristics	See assay kit Technical Data Sheet
Sample Carryover	None, due to single-use cartridge
Sample Type, Sample Volume, Sample Limitations	Assay-specific and test-specific information can be found in the Technical Data Sheet included with assay kit
Cartridge Backbone Material	Cyclic olefin copolymer (COC)

CARTRIDGE DESCRIPTION	SPECIFICATION
Cartridge Automation	<p>The following are general capabilities:</p> <ul style="list-style-type: none"> • Up to three reagent injection steps. Each step enables mixing and incubation time for cell staining. • Automated sample reading. • Automated data analysis, which provides the user with analyzed data file, e.g. event detection record in .fcs and .csv file formats.

Appendix B – Symbols

SYMBOL	USED FOR:
	Manufacturer
	Serial Number
	CE Mark
	TUV Mark
	Consult instructions for use
	Environmentally-friendly use period. The actual number of years may vary by product. This symbol is typically orange in color.

Appendix C – Labels



1. Accellix products may be covered under one or more patents in the U.S. and elsewhere. Additional patents may be pending in the U.S. and elsewhere. This system and cartridge are covered by, or are for the use in the method of the following issued patents: US 9,029,158 US 9,234,884 US 9,535,059 US 9,757,729

Appendix D – Safety Information

- **Laser exposure:** Do not open the Cartridge Access Door while the instrument is processing a sample, as this will cause the assay to be aborted. This is designed to prevent the user from being exposed to the laser while the laser is active.
- **Cartridge- and assay-specific safety issues:** Refer to the Technical Data Sheet included with assay kit.
- **Cartridge disposal:** Dispose of the cartridge as a biohazard in accordance with local regulations.
- **Electrical safety:** The instrument complies with the following standards:
 1. IEC/EN61010-1
Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements
 2. IEC/EN 61010-2-081
Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes
 3. EN61326 EMC emission and immunity requirements
 4. FCC compliance statement: This instrument complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:
 - a. This instrument may not cause harmful interference, and
 - b. This instrument must accept any interference received, including interference that may cause undesired operation.
 5. Per China MIIT Notice No.52 on regulation of micropower equipment:
 - a. The use of the equipment shall comply with the specific provisions and usage scenario, type and performance of the antenna adopted, and the method to control, adjust and switch the equipment in the “Catalogue of Micro-power Short-range Ratio Transmission Equipment and Technical Requirements”;
 - b. It is not allowed to arbitrarily change the usage scenario or usage condition, expand the transmission frequency range, increase the transmission power (including additional installation of radio frequency power amplifier) or arbitrarily change the transmission antenna;
 - c. No harmful interference may be caused to any other legitimate radio station, and no protection against harmful interference may be required;
 - d. It shall withstand the interferences from industrial, scientific and medical (ISM) application instruments radiating RF energy or interference from other legitimate radio stations;
 - e. If harmful interferences are caused to other legitimate radio stations, the use of radio transmission equipment shall be stopped immediately, and can only be continued after measures have been taken to eliminate the interference;
 - f. For the use of micro-power equipment in aircrafts, in military and civil radio stations established according to the laws & regulations and relevant regulations of the state, such as the radio observatories, meteorological radar stations, satellite earth stations (including measurement and control station, ranging station, receiving station and

navigation station), in airports and other electromagnetic environmental protection areas, it is required to comply with the provisions for electromagnetic environmental protection as well as the regulations of competent authorities of relevant industries;

- g. No remote controller is accessible to the area centering at the center point of runway and in 5000 m radius;
- h. The environmental conditions of temperature and voltage in the use of micro-power equipment shall meet the operating environment and electrical requirements outlined in **Appendix A – Technical Specifications**.

Note: Protection provided by the equipment can be impaired if the instrument is used in a manner not specified by the manufacturer.

Appendix E – User Support & Manufacturer Contact Information

Accellix User Support

Accellix, Inc.
2385 Bering Drive
San Jose, CA 5131, U.S.A.
Tel: +1 650.396.3035
Email: support@accellix.com



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