



User Manual

SPC-060 Revision 01.1

March 2021

© Copyright 2021 Accellix Inc. All rights reserved.

Accellix is a trademark of Accellix Inc.

All trademarks used herein are the property of their respective owners.

Table of Contents

About the Accellix Platform	2
Intended Purpose	2
Principles of Operation	3
Overview of Operating Elements	4
First Time Installation	6
Installation of Computer Hardware	6
User Logins	8
Main Administrator Screen	10
Adjusting the instrument's settings	14
Administrator Settings	17
Operating the Accellix Platform	26
Shutting Down the Instrument	35
Troubleshooting	36
Cartridge Issues	36
Instrument Issues	37
Handling Instructions	38
Maintenance	38
Assay-Specific Information	39
Appendix A – Technical Specifications	39
Appendix B – Symbols	41
Appendix C – Safety Information	41
Appendix D – User Support & Manufacturer Contact Information	42

About the Accellix Platform

The Accellix Platform is a benchtop flow cytometer utilizing a single-use cartridge and customizable analysis software; simple to use, it requires no extensive training nor does it involve complex operational processes. Accellix greatly expands access to flow cytometry capabilities by replacing previously complex process steps with a user-friendly automated instrument and easy-to-use single-use cartridges. Whereas obtaining flow cytometric results normally would require steps such as assay preparation by a highly trained individual, sending samples out to a centralized lab, and analysis of the cytometry data by a highly-trained professional, with Accellix these steps are simplified or eliminated.

Using the Accellix Platform, flow cytometric results can be obtained rapidly, even at the site where a specimen is produced. For biotech industry researchers and product developers alike, Accellix provides a flexible platform to streamline the development of customized assays. In addition, Accellix can be utilized in quality assurance and quality control (QA/QC) processes in the immunotherapy field, reducing time and costs in the treatment of patients while increasing reproducibility. In all these cases, utilization of the Accellix platform eliminates transport time, wait time at the processing lab, reduces training time to an hour with a simplified workflow and decreases variability by automating sample preparation to analysis in just 30 minutes.

In other applications, using Accellix can increase efficiency and reduce costs. As the Accellix instrument is more compact than most existing flow cytometry systems, it is uniquely suited for point-of-need (PON) flow cytometric applications, as well as for use as an in-line process analytical technology (PAT) in biologics manufacturing processes.

In summary, the Accellix Platform automates and simplifies sample preparation, provides a user-friendly interface, and yields reliable results, all while using single-use cartridges. Accellix also provides automated data analysis, reducing the need for access to a trained professional and increasing the consistency of this process.

Intended Purpose

Note: This document provides instructions regarding the Accellix Instrument. For instructions regarding Accellix cartridges and associated assay reagents, refer to the Technical Data Sheet and Instructions For Use of the relevant assay.

The Accellix Platform is intended to perform the flow cytometric measurement of analytes in biological samples, using cartridges designed specifically for use with the Accellix Instrument. The instrument is intended to be used with an Accellix Cartridge. In addition to supporting rapid assay development, Accellix can be utilized for applications requiring customized assays, such as cell engineering, as an automated quality control (QC) tool.

Two types of assays have been developed for the Accellix:

- Off-the-shelf assays these include generic assays which are used throughout research & development of cell products. Among others, Accellix offers a T cell panel, for monitoring T lymphocyte populations, a TBNK panel for general lymphocyte populations and a stem Cell panel for monitoring hematopoietic stem cell populations.
- **Customized assays** the Accellix Platform's flexibility enables migration of user-specific assays onto the instrument. During a joint development process, customized cartridges are developed

based on the user's specific needs. For example, customized assays are developed to streamline the QC monitoring process for manufacturing and releasing cell therapy products.

Principles of Operation

The Accellix Platform is based on the general principles of flow cytometry, and combines 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:

- Biochemical sample preparation—*i.e.*, the assay
- Flow cytometric data acquisition
- Reporting of the events detected in a format which readily permits further analytical data processing. Algorithm-based autoanalysis of cell populations or manual analysis options is available.

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. Instrument operators need only to perform a few simple operational steps which entail very limited training. Specialized skills and/or extensive laboratory experience are not required.

Mode of Operation

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

- 1. User selects the cartridge which is suited for the desired assay.
- 2. User introduces assay specimen into the Accellix Cartridge (See Technical Data Sheet and Instructions For Use for cartridge-specific preparation instructions) and closes the plug or seal to create a closed system.
- 3. User taps the **Start** icon on the Accellix Instrument touch screen. The assay process begins.
- 4. User follows the step-by-step instructions on the instrument touchscreen.
- 5. User opens the Accellix Instrument door, inserts cartridge, and then closes instrument door.
- 6. 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. User is prompted to enter a sample ID and kit number (note that the kit number may not be configured for all devices). This information can be entered using the on-screen keypad on the touchscreen, an external keyboard connected via USB port, or by using a barcode scanner.
- 8. The user is required to confirm that sample ID and cartridge type that have been recorded are correct before proceeding to run the assay.

- 9. A progress indicator is displayed on the instrument screen, giving an indication as to the time remaining until the completion of the assay.
- 10. The assay proceeds automatically, including the execution of the flow cytometric reading and analysis of the data acquired.
- 11. At assay conclusion, messages on the instrument screen notify user that assay has been concluded.
- 12. Depending on the specific assay which has been run 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 designed for a specific test type.).
- 13. Following the assay, the single-use cartridge is removed from instrument by user and disposed in a receptacle for biohazard waste.
- 14. After instrument door has been closed, instrument screen returns to the **Home** screen, and the next assay can be started.

Overview of Operating Elements

The Accellix Platform is composed of a benchtop flow cytometer instrument, a single-use cartridge, and customizable analysis software available separately.

The Accellix Instrument is operated using the touchscreen display, as shown below 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. A description of how to use each Accellix cartridge type is provided in the assay's Technical Data Sheet.



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.

First Time Installation

Product Contents

PART #	DESCRIPTION	QTY.
AS-00150	Accellix Flow Cytometer	1
CS-00070	Biohazard Bag	1
CSE-00273	WiFi Antenna	1
CSE-00680	Power Supply Cable (interchangeable for multiple geographical regions)	1
CSE-00551	Ethernet Cable	1

- Unpacking and installing the Accellix Instrument is a procedure which should be performed only by an Accellix Field Application Scientist.
- The original shipping case should be returned to the manufacturer following installation of instrument.

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

Certain assay types generate data files that are intended to be copied to a user-selected destination. Therefore, the user may wish to attach an external drive to the instrument to copy data files. In this case, the user should carefully connect the drive to the instrument at one of the four USB ports on the rear panel.



Figure 4: View of rear panel of Accellix Instrument

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

- Internet connectivity In order 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). In addition, 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 by connecting the printer-USB cable to one of the USB ports on the rear of the instrument, or by connecting to a network printer via ethernet cable or Wi-Fi.
- 4. **Peripherals** If needed, e.g. for troubleshooting or touchscreen issues, a mouse and/or keyboard can be connected to the instrument using 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.

User Logins

If a device is configured to require user logins, the **User Login** screen (Figure 5) is displayed when the device starts up. (If user logins are not required, the device will start up as described below in *Operating the Accellix Platform*.)



Figure 5: The User Login Screen

There are two types of users with two distinct capabilities: Administrators and Operators.

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

Log in as an Administrator in order to perform any of the following tasks:

- Create new users
- Configure login options
- Set system parameters (see chapter on Administrator Settings)
- Copy Activity Log

TO LOGIN:

- 1. Select a user from the list.
- 2. Enter that user's password.
- 3. Tap the **Log in** icon **Control** 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 Weat and the **Next** icon **Fee**

TO CHANGE PASSWORD:

1. Tap the Change Password icon

. The **Change Password** screen (Figure 6) is displayed:

Accellix	
Change password for: Saily Password: 	
Aa Password muse contain at least one: - Lower case letter - Upper case letter	
- Opper Gase letter - Number - At least 8 characters You may use any character except semi-colon (;)	

Figure 6: Change Password Screen

2. Enter the new password twice, identically.

The **Ok** icon <u>only</u> becomes active if both passwords entered are identical and any other conditions are met. Possible password conditions are:

- Minimum password length is 8 characters
- Must contain at least 1 upper-case letter
- Must contain at least 1 lower-case letter
- Must contain at least 1 number
- May contain any symbol (e.g., #@%, etc) except semi-colon

A new password cannot have been previously used by any user.

Tap the **Next** icon to display the **Home** screen (Figure 14).

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

Main Administrator Screen

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



Figure 7: Main Administrator screen

As many as 4 icons are displayed:

- Personnel (adding and editing users and log in options)
- Copy Activity Log (copies the activity log to designated backup location)
- General Administrator (described in chapter Adjusting the Instrument's Settings)
- Logout

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

TO CHANGE PERSONNEL:

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



Figure 8: Personnel screen

The **Personnel** screen has three options at the top: **Administrators**, **Operators** and **Parameters**.

When **Administrators** or **Operators** is selected, the software allows for the addition, unblocking, activating or deactivating of the respective user.

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

KEY:

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

Accellix SPC-060-EN Accellix User Manual – Rev. 01.1, Mar. 2021

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 **I** only becomes active when a valid username is entered.

Note: A username cannot be blank or consist of only spaces, nor can it contain any of the following characters: $* \setminus / ": < > ? | _ % # & { } $! ' @.$

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.

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 **Sec.** The changes are saved.

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 number of minutes to wait to reset "number of failed attempts" to zero if "Max failed Login attempts" not yet reached.
Max days between new passwords:	Sets the number of days to transpire between the last time a user changed his/her password until it is required to be changed 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.

Adjusting the instrument's settings

The instrument should be configured for use by adjusting instrument settings, according to the following steps:

1. Turn on the instrument by switching the **Power switch** on the rear panel of instrument to the '**ON**' position. While the instrument boots up, display will inform user that **System Self-check** is being performed (Figure 11):



Figure 11: 'System Self-check' screen

2. Verify that system has successfully completed initialization, and that the **Home** screen appears on instrument display (Figure 12).

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



Figure 12: Home screen

3. Tap the **Settings** icon at the bottom right of the **Home** screen to access the **Settings** screen (Figure 13).



Figure 13: 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 a checkbox is not selected, the results will not be printed automatically at the conclusion of a test run. However, even if automatic results printout is not selected, the user can manually print the results from the **Results** screen at test conclusion.

Note: Results printing functionality is only relevant for assay tests that support automatic results reporting and printing.

- Language Select a language from the list under Language.
- Instrument Date/Time Display The date and time set on the instrument are viewable from this screen along with the name of the device and the current version of the software.



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

Administrator Settings

The settings on the instrument that are meant to be defined and/or changed by an "Admin user" are accessed as follows:

- 1. Tap the **Administrator** icon icon at the bottom center of the **Home** screen (Figure 12).
- 2. Enter the password in the Admin User Password Input window (Figure 14) to access the General Administrator Settings screen (Figure 15).

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



Figure 14: Admin User Password Input window

Note: To receive the Admin password, the user who has been authorized to act as the instrument administrator should contact Accellix Support at support@accellix.com. 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 15: Administrator screen

- 3. On the Administrator screen, the user can enter or adjust the following settings:
 - View and print all results —

Displays a list of all results measured on this device which can be viewed and printed (Figure 16).

	Time	Sample ID	Cart ID	Assay
06/05/2018	18:23	5.1	123456	GP0
06/05/2018	18:23	5-1	123456	GP0
06/05/2018	18:23	5-1	123456	GP0
06/05/2018	18.23	5-1	123456	GP0
06/05/2018	18:23	5-1	123456	GP0
06/05/2018	18:23	5-1	123456	GP0
06/05/2018	18.23	5.1	123456	GP0
06/05/2018	18:23	5-1	123456	GP0
06/05/2018	19:55	6-1	123456	GP0
06/05/2018	19.55	6-1	123456	GP0
06/05/2018	19:55	6-1	123456	GP0
06/05/2018	19:55	6-1	123456	GP0
06/05/2018	19.55	6.1	123456	GP0
06/05/2018	19:55	6-1	123456	GP0
06/05/2018	19:55	6-1	123456	GP0
06/05/2018	19:55	6-1	123456	GP0
09/05/2018	16:30	66	123456	GP0
09/05/2018	16:38	99	123456	GP0
16/05/2018	11:46	66	123456	GP0
19/07/2018	11:37	33	1	DRG
30/08/2018	17:38	99	100380	GP0
30/08/2018	17:38	99	100380	GP0
30/08/2018	17:38	99	100380	GPO

Figure 16: All Results screen

• Assay Admin —

This feature is used to generate signature matrix files for each assay using previously acquired data (Figure 17).

	Assay DVS G171 G172 GP0 G3100	ĺ
	GT0 P101 P102 Calculate Signature Ma	XI
04		(P)
TCR		100
/631		12
03		100
CDE		ie.

Figure 17: Assay Admin screen

• LIMS Database connection —

This screen can be used by the Admin user to configure settings to connect the Accellix Instrument to a site LIMS Database that uses the same protocol (H7). Admin user can input LIMS address using the on-screen keyboard, which is accessed by tapping the Aa icon next to this field (Figure 18).

Accellix
Save results to LIMS Print after saving to LIMS LIMS Address
6661 Aa
IIIII Free Virtual Keyboard (ww — — — — ** 1 2 3 4 6 7 8 9 6 7 ** 4 * * * 9 * * • •
tem a d f g h j j h j h j h j h j h j h j h j j j j j j
K Back

Figure 18: LIMS Configuration screen

• Copy Previous Results function -



Admin user can copy results files from past test runs by selecting a date range (Figure 19), and tapping **Copy Now**. Cartridge data folders which fall between the selected dates are displayed below the two calendars.

• If the check box next to **Copy raw data files** is selected, the software will also copy raw data files in addition to results files for past tests.

The copy destination is selected in the **Destination Location** function, as explained below (Figure 22).

•	_									een:					
		Octob	ber 20	19		,	F	•		1	Vover	nber 2	019		
Sun 40 29 41 6 42 13 43 20 44 27 45 3	Mon 30 7 14 21 28 4	Tue 1 8 15 22 29 5	2 9 16 23 30 6	Thu 3 10 17 24 31 7	Fri 4 11 18 25 1 8	Sat 5 12 19 26 2 9	•	14 15 16 17 18 19	Sun 27 3 10 17 24 1	Mon 28 4 11 18 25 2	Tue 29 5 12 19 26 3	Wed 30 6 13 20 27 4	Thu 31 7 14 21 28 5	Fri 1 8 15 22 29 6	5
	k		G P T T T	P0 (103 C10 C10 C10 C10	CID-I CID 0 CII 0 CII 0 CII	-0-11 0-102 -0-11 D-0-1 D-100 D-191 aw d	2009 200 030 0-00 1018	960 84 10 02 3-1) 2 69 62 030	014:					
						opy I	B								

Figure 19: Copy Results Files screen



• Copy Test Runs with Errors function —

Files related to test runs for which errors were generated can be selected and copied by tapping the **Copy** icon (Figure 20). Individual cartridge data folders can be selected together by using the Control key when clicking on an entry in the list.

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 22).



Figure 20: Copy Test Runs with Errors screen

'Delete Raw Data' function —

•



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.



Figure 21: Delete Raw Data files screen

• Copy function: — Copy

This setting determines what results should be copied to the destination location at the conclusion of an assay run. If the checkbox next to "**Delete after copy**" is selected, a cartridge's entire data folder will be deleted from the internal hard disk after being successfully copied to the destination location (Figure 22).

• Destination Location - The destination where the results should be copied to is displayed in the

field directly below the **Delete after copy** checkbox. Set the path by using the folder icon **next** to the destination location field (see red box in Figure 22).



Figure 22: Copy and Destination Location section

Tapping the folder icon displays the **Set Data Destination Configuration** screen (Figure 23):



Figure 23: Set Data Destination Configuration screen

- The pop-up menu allows the user to navigate up the hierarchy of the folder structure. The currently selected folder is the one at the bottom of the hierarchy.
- 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.

KEY:



Saves the current folder as the destination for all data to be copied.



Cancels any changes and leave the destination location as it was before entering this screen.

Rescans the currently selected folder and updates the list of its contents.

Note: All files, including raw data files, results reports, etc., generated by 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 by Accellix Support, upon user's request.

Note: The raw data (.bin) files are each approximately 1.25 GB.

Operating the Accellix Platform

To successfully operate the Accellix Platform, an operator is expected to undergo basic training procedures which include instructions on operating the instrument, safety procedures, troubleshooting techniques, and instructions regarding the instances when the manufacturer should be contacted for service. This training should be performed by an Accellix Field Applications Scientist, or by an experienced operator who has 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 particular assay.

TO PERFORM A TEST ON THE INSTRUMENT:

- Introduce specimen into the cartridge, according to the relevant protocol for the cartridge type. (Refer to the Technical Data Sheet for detailed instructions for each Accellix assay.)
 After the sample plug/seal has been closed, the test should be started without delay.
- 2. On the 'Home' screen display, tap the 'Start' icon 📩

Note: From this point forward, the progress of the test procedure can be monitored by noting which of the gray dots that appear at the bottom of the screen is currently highlighted.

- 3. Prepare to insert the closed cartridge which has been properly loaded.
- 4. When prompted by the screen (Figure 24), open the door by pressing down on the front righthand corner of the door and releasing. Insert the cartridge into the instrument until a click is heard, ensuring that the cartridge has been inserted fully into the instrument Cartridge Handling Unit (CHU).



Figure 24: Insert Cartridge screen

Note: Another method to start a run is simply to open the door, insert a cartridge and close the door. This will bypass the "Insert cartridge and close door" screen.

5. The screen instructs the operator to wait while the instrument reads and registers the information contained in the QR code on the cartridge (Figure 25).



Figure 25: Reading Cartridge QR Code screen

6. Enter Sample ID screen (Figure 26) - enter Sample ID using the on-screen keypad/keyboard or by using an external keyboard or barcode scanner. The Sample ID will then be displayed on all subsequent screens of the test run.

Note: It is not possible to continue until at least one character has been entered. This may not be any of the following characters or only spaces: $* \setminus / ": < > ? \mid _ \% \# \& \{ \} $! ` @.$



Figure 26: Enter Sample ID screen

- 7. Once the Sample ID field is no longer empty, the Next icon will appear.
- 8. Tap **Next** to continue.

9. **Confirmation screen** (Figure 27) - The instrument screen now displays assay/cartridge type and Sample ID for the operator to confirm before commencing the assay run. Confirm that the values are correct by tapping **Next**.



Figure 27: Confirm Sample ID and Assay/Cartridge screen

Note: Tapping on the **Home** icon aborts this assay and returns to the **Home** screen, after performing a self-check and requiring the user to remove the cartridge and close the door. This is useful in case incorrect information was entered or the run needs to be stopped for any reason.

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

10. **Progress screen** (Figure 28) displays a progress indicator and **Time Remaining** countdown timer. The operator can monitor the test progress and approximate time remaining.



Figure 28: 'Progress Indicator and Time Remaining' Screen

Aborting a Running Assay – Take caution not to inadvertently open the instrument door during an assay run, as opening the door will abort the assay underway. 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: If an operator wishes to stop an assay while underway, this should be done by tapping **Stop**, i.e., the red hand at the center of the progress indicator (Figure 33). Refer to *Termination of an Assay Run* section below.

11. **Results display**: When the test has been successfully completed, the instrument informs the operator by displaying any one of 4 results screens (depending on how the assay is configured): No Results, Pass/Fail, only Total Bead Count or an on-screen table with all results.

The following two screens are examples of potential result displays (Figure 29 and Figure 30):



Figure 29: Example of 'Run Complete' screen

Results	Value
Name	
CD3+ Viable/ CD45+ Viable[%]	99.62
CD4+ Viable/ CD45+ Viable[%]	57.99
CD8+ Viable/ CD45+ Viable[%] CD3T+ Viable/ CD3+ Viable[%]	34.11
CD4T+ Viable/ CD4+ Viable[%]	1
CD8T+ Viable/ CD8+ Viable[%]	1
Total Bead Count	5364

Figure 30: Example of On-screen Results report



- a. For a test 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 30.
- b. For a test 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 test.
- c. If automatic printout was not configured, or if the operator chooses to print to an

alternate printer, a manual printout can now be initiated by clicking on the **Printer** icon at the bottom-left of the **Results** screen. Operator may select desired printer from the **Printers** list, and then tap **Printer** icon to execute the manual printout.

Note: If the assay/cartridge type is not intended to produce an on-screen **Results** display at its conclusion, no printout will be generated.

12. Tap the **Next** icon when ready to conclude the test process.

On-screen instructions (Figure 31) prompt operator to open instrument door, then remove cartridge, and finally to close instrument door.

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



Figure 31: Remove Cartridge screen displayed following conclusion of test

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

TO RUN A MULTI-CARTRIDGE ASSAY:

1. The **Multi-cartridge Remove Cartridge screen** instructs the operator to remove the current cartridge and insert the next cartridge in the sequence (Figure 32).



Figure 32: Multi-cartridge Remove Cartridge screen

2. If the operator does not insert the correct type of cartridge, the operator is instructed to remove that incorrect type and insert the correct type (the software scans the QR code upon insertion of the next cartridge to determine if it is of the correct type to run next).

Note: The operator 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 Enter Sample ID screen (Figure 26) and continue with that cartridge.

TERMINATION OF A TEST RUN:

The **Stop** or **Abort** icons may be used to terminate a test run (Figure 28 and Figure 32).

If a test is stopped during the run, a message is shown on the screen (Figure 33), while the system returns

the cartridge to home position. Homing of cartridge may take some time, as the test scripts must be aborted and internal motors moved to their home positions.



Figure 33: On-screen message following termination of test run

Note: Only after on-screen display instructs operator to remove cartridge should operator attempt to remove cartridge from instrument.

Shutting Down the Instrument

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

TO SHUT DOWN THE INSTRUMENT:

1. On the **Home** screen, tap the **Shutdown** icon **O**. The operator is prompted to confirm the shutdown (Figure 34)



Figure 34: Confirm Shut Down screen

2. Tap the **Shutdown** icon to start the power down sequence. Once the device's screen is black it is safe to turn off the physical power switch on the rear panel of the device.

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

Troubleshooting

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

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

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

Specific instructions for each error type are provided on-screen (Figure 35).



Figure 35: Example of Error Message

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

Instrument Issues

With the exception of Hard Disk Full warning (see below), recovery from all other anomalous behavior of

the device can be performed by tapping the **System Self-Check** icon or by turning the device off and then back on. If the System Self-Check/Restart does not help, report the error to Accellix Support.

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:

The exception to most hardware-related instrument issues is when the device's hard disk is full. The Accellix Instrument stores data files generated for each assay on its internal hard disk, which may become nearly full after a certain number of assay runs. Thus, prior to executing an assay run, the instrument checks that a minimum amount of hard disk space is available to be able to successfully complete an assay run. If the **Hard Disk Full** warning (Figure 36) is displayed, hard disk space must be freed to execute further assays.



Figure 36: Hard Disk Ful' warning screen



Hard disk space can be freed by the Admin user using the '**Delete Raw Data'** function — **W** (see instructions regarding Figure 21 above in Administrator Settings). If further assistance is needed, contact Accellix Support.

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 *Installation of Computer Hardware* above.

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. If instrument performance issues are suspected, contact Accellix Support.

If the system does not start, or for further troubleshooting instructions, Accellix Support should be contacted.

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:
 - Ambient Temperature: 20-25°C (68-77°F)
 - o Max. Rel. Humidity 85%, Non-condensing
- For information on instrument dimensions and power, refer to Appendix A Technical Specifications.

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 provided by the error messages. (See *Troubleshooting* section above.)
- 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 — If the instrument is to be connected to a local area network (LAN), Wi-Fi network, or to a network

printer, this should be performed in consultation with qualified IT personnel. (Connection to a user LAN should be performed using a cable less than 3 meters in length.)

- Cleaning the System Accellix instrument may require cleaning from time to time. In order to
 maintain the integrity of all Accellix components, perform cleaning according to the following
 procedure: Wipe the affected instrument surface with a Pursept[®] disinfecting wipe cloth. Follow
 the directions provided with the cleaning product.
- Decontamination If a cartridge is damaged after having been 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 and then wrap a Pursept[®] or Medipal[®] wipe around a

long Q-tip and use it to thoroughly wipe the CHU opening. 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 No servicing is to be performed by the user. All servicing is to 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 <u>www.accellix.com</u>.
- Shipment for Service 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. Following usage where the instrument is considered contaminated, it should be enclosed in the provided biohazard bag, and then placed inside the shipping container.
- Calibration The instrument performs a self-check to ensure that the functionality of the instrument is tested. If calibration is required for a certain cartridge or assay type, the details of the nature and frequency of the calibration needed to ensure that the instrument operates properly and safely will be described in the Technical Data Sheet for each assay kit.

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.

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	Ambient Temperature: 20-25°C (68-77°F)
	(max. rel. humidity: 85%, non-condensing)
	System should be protected from exposure to direct sunlight, humidity, & dust
Excitation Laser	488nm, cyan (40-50mW)
Fluorescence Detector	High-performance SiPM (silicon photomultiplier) array (11 channels)

Appendix A – Technical Specifications

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: 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 Technical Data Sheet included with assay kit.
Cartridge Backbone Material	Cyclic olefin copolymer (COC)
Cartridge Automation	 The following are general capabilities: 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	Symbol	Used for
	Manufacturer	C US	TUV Mark
SN	Serial Number	i	Consult instructions for use
CE	CE Mark		

Appendix C – 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:
 - o IEC/EN61010-1: 2010

UL61010-1 / CAN/CSA - C22.2 No. 61010-1-12

Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements

o IEC/EN 61010-2-081: 2015 (ed.2)

CAN/CSA-C22.2 No. 61010-2-081:15

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

o EN61326 EMC emission and immunity requirements

FCC compliance statement: This instrument complies with part 15 of the FCC Rules.
 Operation is subject to the following two conditions:

(1) This instrument may not cause harmful interference, and (2) this instrument must accept any interference received, including interference that may cause undesired operation.

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

Appendix D – User Support & Manufacturer Contact Information

Accellix User	Accellix, Inc. 2385 Bering Drive			
	San Jose, CA 95131, U.S.A.			
Support	Telephone: +1 650.396.3035			
	E-mail: support@accellix.com			
	Accellix, Ltd.			
	5 Shlomo Momo Halevi Street			
	2nd Floor, Pier B;			
	Har Hotzvim			
	P.O. Box 45409			
	Jerusalem 9777019, Israel			
	Tel: +972-2-674-4422			
	E-mail: office@accellix.com			