



Using CytExpert for DxFLEX Software for User Management and Process Control

Tina Feng | Beckman Coulter, Suzhou, China
 Carsten Lange | Beckman Coulter, Krefeld, Germany
 Jeffrey Short | Beckman Coulter, Indianapolis, USA

IN THIS PAPER YOU WILL

Discover important functions of the CytExpert for DxFLEX software for any clinical flow cytometry lab

Learn how CytExpert for DxFLEX automates instrument Quality Control

Find out how the Standardization tool enables users to easily adjust settings to standardize their results from day to day

DxFLEX is a flow cytometer developed by Beckman Coulter Life Sciences for clinical use. In addition to its advanced hardware design for high sensitivity and resolution—and multiple-color detection capability—this system also provides many tools to help users better control access to the software via different authority levels. The new process control for **analysis** and **review** make it easier to control changes and ensure data integrity.

User management and user control

The software provides two types of accounts by default: **Administrator** and **Operator**.

Only **Administrator** users can access the full functionality of instrument settings, as shown in Table 1.

Table 1: Account Authority

	Administrator	Operator
Manage user accounts	Y	N
Set up account policy	Y	N
View operation log	Y	N
Modify settings in Advanced menu	Y	N
Modify Cytometry settings	Y	N
Manage panel template library	Y	N
Manage QC/Standardization target value files	Y	N
Delete QC results	Y	N
Backup/restore software database	Y	N
Access Analyze function	Y	N
Access Review function	Y	N

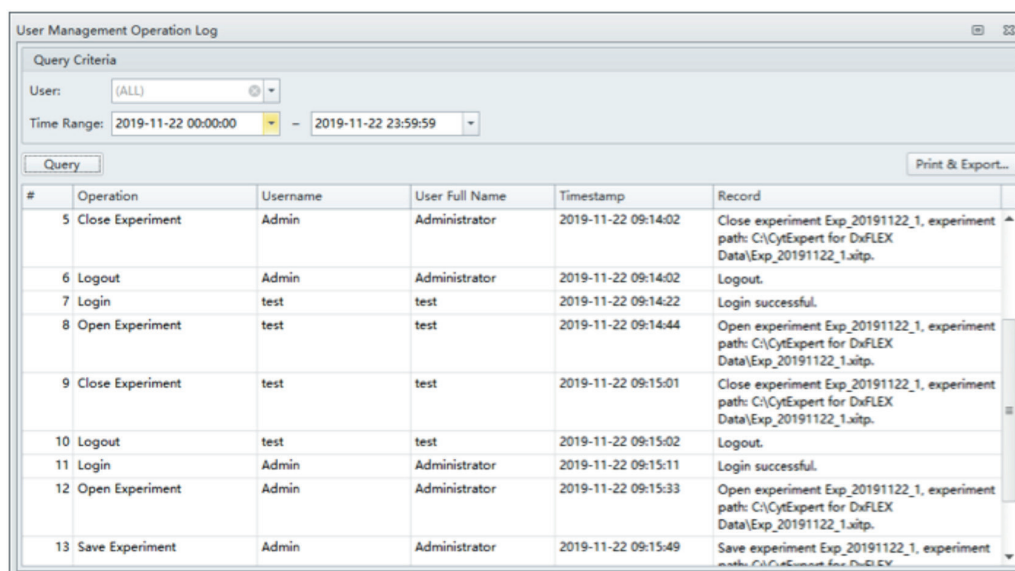
In addition to the two default account types, Administrator users can add more types of roles with different levels of system control. This can help further avoid potential risks from unauthorized users erroneously changing system settings.

To fulfill varying requirements from different types of labs, account policies can be assigned. All these policies focus on password safety.

Table 2: Account Policy

Account Policy	Explanation
Password complexity requirement	Once enabled, the password must: 1. Be at least 10 characters in length 2. Contain characters from all four of these categories: English uppercase characters English lowercase characters Base 10 digits Non-alphabetic characters
Enforce password history	Historical password cannot be reused (includes at least 12 previous passwords).
Enforce minimum password length	Password must be a minimum of 10 characters.
Enforce minimum password age	When a new password is saved, it cannot be changed again before reaching the minimum age.
Enforce password expiration	Password will be forced to expire after a pre-set number of days, and users must change their password before logging into the system.
Enforce account lockout duration	Users can try to access their account only a limited number of times, after which they are locked out. Administrator accounts can contact Beckman Coulter to reset their password; operator accounts can be reset by Administrator accounts—or operators can wait a pre-set length of time before they can try again.
Enforce application lock	If no operation has been made to the application for a certain amount of time, the application would be locked, and a current user must enter a password to unlock it.

The log file (shown below) includes key operations of different accounts. **Administrator** accounts can review the log file to identify who has made changes to which experiments and when. This can help labs meet audit trail requirements.



The screenshot shows a window titled "User Management Operation Log". It has a "Query Criteria" section with "User:" set to "(ALL)" and "Time Range:" from "2019-11-22 00:00:00" to "2019-11-22 23:59:59". Below this is a "Query" button and a "Print & Export..." button. The main area is a table with the following data:

#	Operation	Username	User Full Name	Timestamp	Record
5	Close Experiment	Admin	Administrator	2019-11-22 09:14:02	Close experiment Exp_20191122_1, experiment path: C:\CytExpert for Dx\FLEX Data\Exp_20191122_1.xitp.
6	Logout	Admin	Administrator	2019-11-22 09:14:02	Logout.
7	Login	test	test	2019-11-22 09:14:22	Login successful.
8	Open Experiment	test	test	2019-11-22 09:14:44	Open experiment Exp_20191122_1, experiment path: C:\CytExpert for Dx\FLEX Data\Exp_20191122_1.xitp.
9	Close Experiment	test	test	2019-11-22 09:15:01	Close experiment Exp_20191122_1, experiment path: C:\CytExpert for Dx\FLEX Data\Exp_20191122_1.xitp.
10	Logout	test	test	2019-11-22 09:15:02	Logout.
11	Login	Admin	Administrator	2019-11-22 09:15:11	Login successful.
12	Open Experiment	Admin	Administrator	2019-11-22 09:15:33	Open experiment Exp_20191122_1, experiment path: C:\CytExpert for Dx\FLEX Data\Exp_20191122_1.xitp.
13	Save Experiment	Admin	Administrator	2019-11-22 09:15:49	Save experiment Exp_20191122_1, experiment path: C:\CytExpert for Dx\FLEX

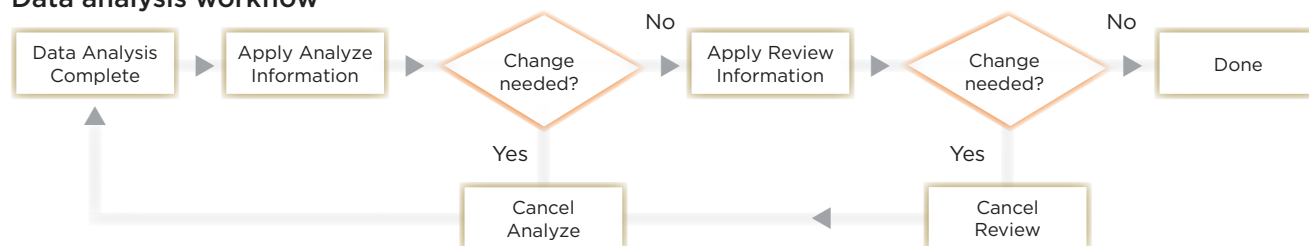
Process control for data analysis

An enhanced workflow for data analysis is established in version 2.0.1.

Results are locked after the **Analyze** function is applied. Authorized users can then add comments using the **Review** function.

If modifications are needed, previous **Analyze** and **Review** information should first be deleted to avoid changes after results are confirmed.

Data analysis workflow

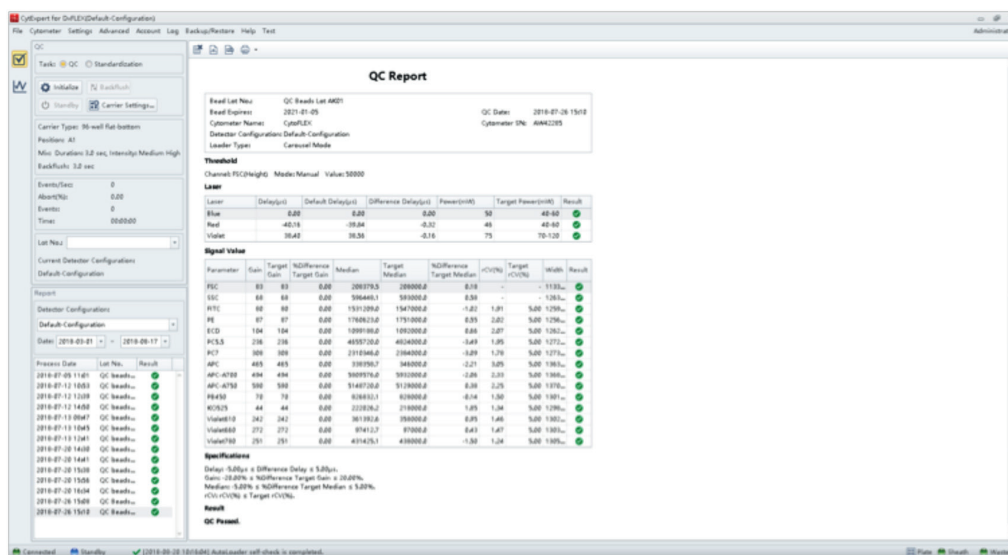


All Analyze and Review information, including account name, date and comments, can be displayed in the reports.

Instrument Quality Control

To ensure data quality, the system provides an automatic QC program for instrument performance. *We suggest running QC once per day before acquiring data to ensure consistent data quality.*

To run instrument QC, users must prepare a tube with DxFLEX Daily QC Fluorospheres, which is ready-to-use (no dilution step required). The software completes the QC process automatically.



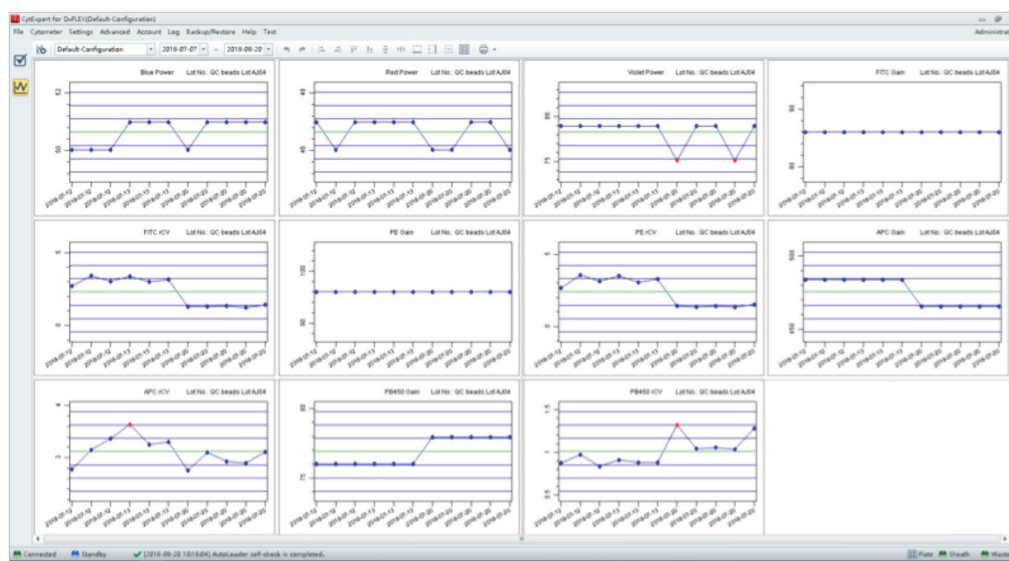
From QC reports, users can review the details of instrument performance, including:

- Laser power
- Laser delays
- Gain settings for all channels to reach the target MFI
- rCVs of all fluorescent channels

The software determines if all laser power data and rCVs are within reference ranges. For other items, the software compares results with the last run to determine if changes are higher than acceptance ranges.

For all items, a check mark indicates that the event passes.

In addition to day-to-day comparisons, CytExpert for DxFLEX software also enables users to track long-term performance with Levey-Jennings charts.

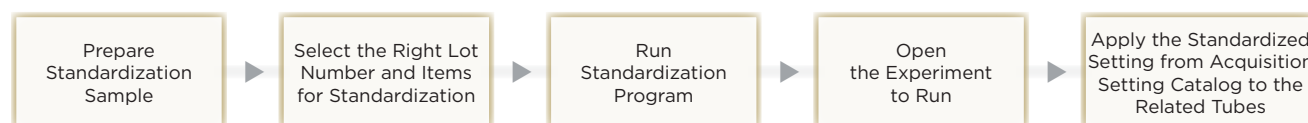


Boundaries can be set according to lab policy. Data points that are out of the lab's set boundaries are displayed in red to clearly alert users.

Standardization and Acquisition Setting Catalog

The Standardization tool enables users to easily adjust settings to standardize their results from day to day. When preparing the instrument for a new experiment, users can optimize settings by creating target values based on the stored settings. These settings can be automatically calibrated day-to-day to ensure use of the same MFIs for the same sample types.

How to use the standardization program



Users can also use **Link to setting from catalog** to link the setting of an empty tube with a setting in the catalog. After a setting in the catalog is calibrated, settings of the linked empty tubes are updated accordingly.



DxFlex flow Cytometer is CE marked for up to 13-color in vitro diagnostic use. This device is not available in all countries. Please check with your local sales representatives before placing your orders.

© 2019 Beckman Coulter Life Sciences. All rights reserved.

Beckman Coulter, the stylized logo, and the Beckman Coulter product and service marks used herein are trademarks or registered trademarks of Beckman Coulter, Inc. in the United States and other countries.

For Beckman Coulter's worldwide office locations and phone numbers, please visit "Contact Us" at beckman.com

FLOW-633212.19