

21 CFR Part 11 Software Console Features

Quick Reference Card

Overview

The 21 CFR Part 11 console is a new feature of the Analysis Software v4.0 for the Applied Biosystems 8200 Cellular Detection System (CDS). The FDA Title 21 Code of Federal Regulations Part 11 regulates electronic records and electronic signatures. The console allows a customer to integrate the 8200 CDS in to the customer's 21 CFR Part 11 compliant workflow. The 8200 CDS with Analysis Software v4.0 is not validated as 21 CFR Part 11 compliant because Applied Biosystems did not perform system level testing of the 21 CFR Part 11 requirements.

IMPORTANT! Your company must ensure that all parts of the FDA regulation are followed. For more information on complying with the FDA Title 21 Code of Federal Regulations Part 11, refer to the FDA website:

<http://www.fda.gov>

The purpose of this quick reference card is to describe the new features that a user encounters when using the 8200 CDS Analysis Software v4.0 21 CFR Part 11 console.

Logging In

The Software System Administrator assigns each user a unique user name and password. Also, each user is assigned to one or more groups that define the user's permission to perform predefined Controlled Activities (activities a user is either allowed to perform or prevented from performing).

Be aware that while the 21 CFR Part 11 console is enabled:

- The Software System Administrator must re-create user accounts for 8200 CDS Analysis Software v3.0 in v4.0. Your login name, password, and group may have changed.
- If your login information is incorrect, the Analysis Software does not start. The Software System Administrator may have set a limit on the number of login attempts after which a user is locked out and subjected to a suspension time.
- The Software System Administrator may have set a password to expire after the first use (such as for a default password) or a password lifetime and reuse suspension time.

Starting the Analysis Software v4.0

After logging in, the 8200 CDS Analysis Software starts and the main screen is displayed. Note that:

- The Software System Administrator may have set the 8200 CDS Analysis Software to prevent accessing a run file that has been altered without using the 8200 CDS Analysis Software (for example, copying data files in to the run file).

To protect the integrity of electronically-stored data, the Checksum feature detects data changed by software other than 8200 Analysis software. The Checksum feature sums the data electronic bits, and stores the resulting value. The value is updated when a user closes a run file, opens or creates a run file, and exits the 8200 Analysis software. The next time data is accessed, the Checksum feature sums the data electronic bits and compares the result to the previous checksum value. If the sums match, the data is accepted as changed only through the 8200 CDS Analysis Software. If the sums are different, the 8200 CDS Analysis Software displays a failed validation message. If permitted, the you can choose to update the checksum value and open the data file as fully accessible. If the checksum value is not updated, the file can be opened as read-only.

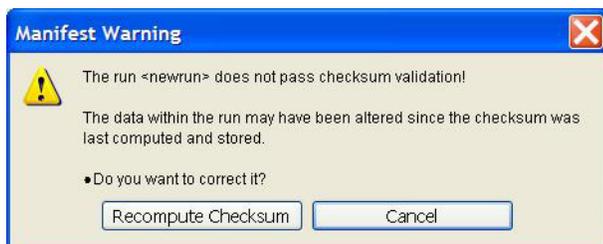


Figure 1 Checksum dialog box

- The Software System Administrator may have set a limit on the amount of time a user can remain inactive (no mouse or keyboard activity) during a session. If the limit is exceeded, you are locked out of the software and prompted to re-enter login information to continue the session.
- Within the Analysis software, you are allowed to perform any activity that is permitted to the User Group you entered at login.

Analysis Software v4.0 New Features Related to the 21 CFR Part 11 Console

Two new tabs are available in the 8200 CDS Analysis Software main screen: **Audits** and **E-Signatures**.

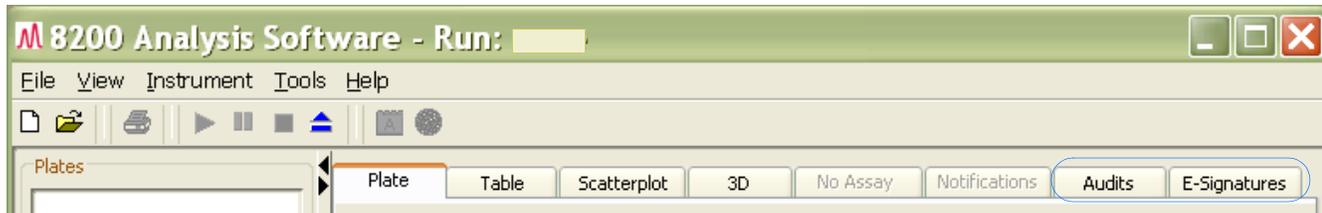


Figure 2 Audits and E-Signatures tabs

Audits

For the life of the run file, the data auditing feature tracks changes to 8200 CDS Analysis Software data by storing audit trails to independently record the date and time users create, delete, or update 8200 CDS data. The Software System Administrator can set the software to prompt for an audit trail comment (see Figure 3), and mandate whether a comment entry is optional or required. If optional, you can click **Cancel** to close the dialog box without entering a comment. If required, you must enter a comment to continue the activity.

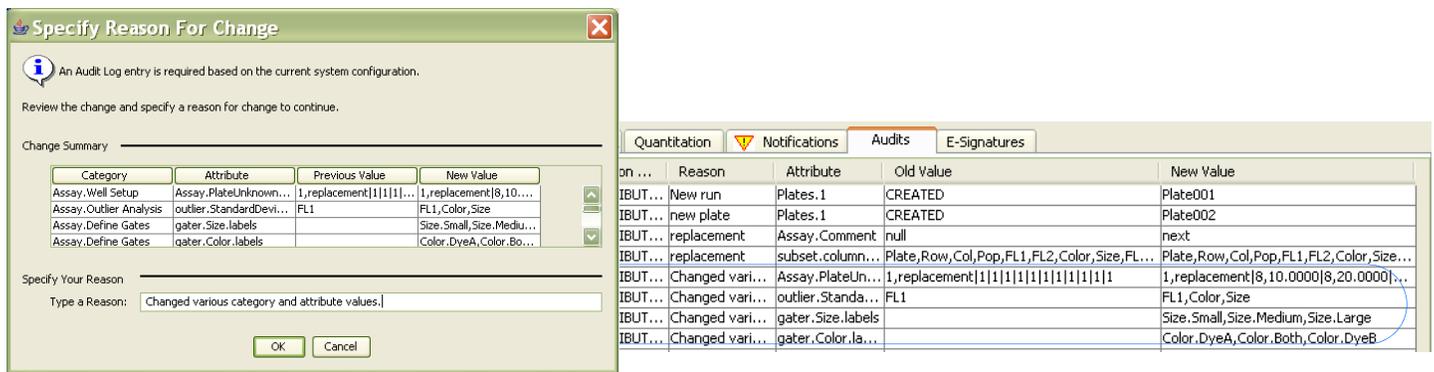


Figure 3 Representative "Specify Reason For Change" dialog box and excerpt from the corresponding audit trail entry

E-Signature

Selected activities may require an E-Signature, whether optional or required. If optional, you can click **Cancel** to close the dialog box and continue the activity. If required, you must enter a signature to continue. When recording an E-Signature, you are approving the current data.

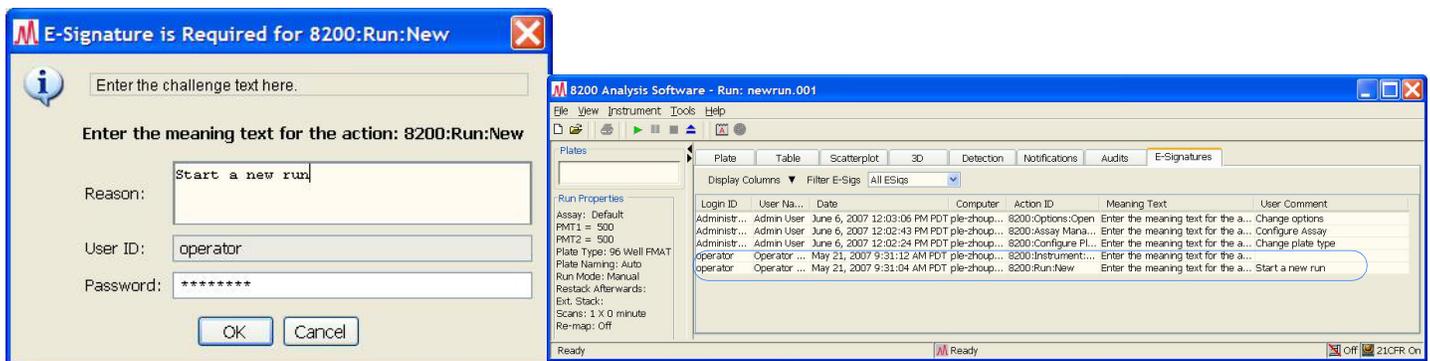


Figure 4 Representative E-Signature dialog box and excerpt from the corresponding E-Signatures trail

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