

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.

Manif	fest Warning	X	
1	The run <newrun> does not pass checksum validation!</newrun>		
	The data within the run may have been altered since the checksum was last computed and stored.		
	•Do you want to correct it?		
	Recompute Checksum Cancel		

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.

🕅 8200 Analysis Sof	itware - Run:	
<u>E</u> ile ⊻iew <u>I</u> nstrument <u>T</u> oo)ls Help	
🗅 📽 🛛 🍯 🕨 🔳 🔳		
Plates	Plate Table Scatterplot 3D No Assay Notifications Audits	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.

🖢 Specify Reason For Change 🛛 🔀		
An Audit Log entry is required based on the current system configuration.		
Review the change and specify a reason for change to continue.		
Change Summary	Quantitation V Notifications Audits E-Signatures	
Category Attribute Previous Value New Value	on Reason Attribute Old Value	New Value
Assay.Well Setup Assay.PlateUnknown 1,replacement[1]1]1 1,replacement[8,10	IBUT New run Plates.1 CREATED	Plate001
Assay.Outlier Analysis outlier.StandardDevi FL1 FL1,Color,Size	IBUT new plate Plates.1 CREATED	Plate002
Assay.Define Gates gater.Size.labels Size.Small,Size.Mediu	IBUT replacement Assay.Comment null	next
	IBUT replacement subset.column Plate,Row,Col,Pop,FL1,FL2,Color,Size,FL	. Plate,Row,Col,Pop,FL1,FL2,Color,Size
Specify Your Reason	IBUT Changed vari Assay.PlateUn 1,replacement[1]1]1]1]1]1]1]1]1]1	1,replacement 8,10.0000 8,20.0000
Type a Reason: Changed various category and attribute values.	IBUT Changed vari outlier.Standa FL1	FL1,Color,Size
	IBUT Changed vari gater.Size.labels	Size.Small,Size.Medium,Size.Large
OK Cancel	IBUT Changed vari gater.Color.la	Color.DyeA,Color.Both,Color.DyeB

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.

E-Signature is Required for 8200:Run:New		
Enter the challenge text here. Enter the meaning text for the action: 8200:Run:New	M 8200 Analysis Software - Run: newrun.001 Efe Yew Instrument Tools Help D B → B = A I Plates	
Reason: Start a new run	Plate Table Scatterplot 30 Detection Notifications Audits Ensignatures Display Columns V Filter Ensigs All Esigs V Login ID User Na Date Computer Action ID Meaning Text User Comment Administ Admin User Na Date Computer Action ID Meaning Text User Comment Administ Administ.	
User ID: operator	PMT1 = 500 Administr	
Ск Cancel	Ext. Stack: Scans: 1.X O minute Re-map: Off Ready MR Peady MO Off	21CFR On

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

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