DSG Density Meter
FDA Reg. 21 CFR part 11 – RFM vs. DSG

BS **Bellingham + Stanley**

a xylem brand

We expect the DSG Series of digital density meters to perform superbly within the pharmaceutical market; in research, raw material testing, manufacturing and of course, quality control itself.

In support of this, both the DSG40 and DSG50 facilitate operation in accordance with FDA reg. 21 CFR Part 11.

However, for those of you who are already familiar with, or using one of our latest RFM900-T refractometers and/or ADP4/600 polarimeters in accordance with FDA reg. 21 CFR part 11, you will spot a few *minor differences* between these instruments and the new DSG density meters.

Essentially, the menu and structure of the instruments are the same recognisable format, it's just a few changes to the way we implement some features. There is nothing critical and both comply. Let's take a look.

Feature	DSG CFR	RFM/ADP* "Enhanced" CFR
Printing	CSV only	XML option for LIMS
	Customisable output	Field selection for customised CSV output
	"Inventory number" on print outs (user defined)	Location traceability on printouts (user defined)
Saved Data	Filter by: Start/End, username, batch, signing status	Multiple new filtering options: Start/End dates, user, batch, method, signing and export status
	CSV and PDF options to USB	CSV and PDF options to USB or FTP
	No scheduled transfer	FTP scheduled export for easy data transfer to LIMS
	Data cannot be deleted	Status flags prevents deletion of data not yet exported to another system
	Up to 100,000 results (4GB expandable memory)	Up to 10,000 results
Electronic Signatures	Multi-user signatures with approve, reject or remove (hide). One-time comment.	Multi-level submitter, reviewer and approver signature levels for pass/fail of results with additional commenting
Audit trail	Up to 100,000 results (4GB expandable memory)	Up to 10,000 events
	Filter by event type only	Additional filter options: event type, user, date range, export status
	One-time comment when change is made to a configuration option	One-time comment on events with date, time and signature of commenter
	Not available	Greatly expanded to cover all new events

Feature	DSG CFR	RFM/ADP* "Enhanced" CFR
Downloading files via FTP	Not available	PDF printouts or any LIMS data, accessible to any users granted the required access rights
	Not available	File integrity checks possible using checksum files
Security features	Auto-login: Choose a user to automatically login at start up. Choosing admin will allow all user access. Chose low level user to limit access.	Optional basic mode: Only two users with simple 3-digit PIN access to either all menus or just measurements routines
	Passwords: lowercase, lower and uppercase or lowercase, uppercase & numbers	Numeric PINS, text passwords or complex passwords enforced
	Password length, strength, change interval, user lockout and auto-logout time selectable	Fully customisable settings to meet user's SOP
	Four defined user types	User Type system. Creatable user types can be assigned to different users to define their access rights, signature level and meaning.
	Not available	Increased access rights to prevent or allow access to different features
	Not available	Printable user/user type lists for easy reference
	System is Methods based. Methods cannot be deleted	Methods cannot be deleted, only hidden (CFR level)
	Auto logout from Menus if idle	Auto logout from Menus if idle
	Unique login name	Unique login name
	Actual name not unique (allows specifying user role). (Username is used for signature)	Unique Actual name (signature)
System clock	Can be synchronised to an internet time server	Can be synchronised to a local time server
System backup	Schedule snapshot for configuration settings to internal memory.	Scheduled reminders to USB. Automatic to FTP allowing automated export to computer server. Can use all features without requiring USB stick.
SSO	Not available	Synchronise user passwords with those on the network – only one set of user credentials to remember
Users	Significant number of users (assume unlimited based on memory limits)	Up to 197 new users can be added

If you have any questions relating to the above, or wish to discuss data integrity (DI) or the validation of one of our instruments in your laboratory, please contact our technical team and we will be more than happy to help.