

## 21CFR Part 11 Compliance Matrix

**This Matrix states how the Brookhaven Instruments *BI-PSD21* software for particle sizing is complying with 21CFR Part 11.**

Section	Ruling	Comment
11.1	Scope.	BIC accepts the purpose and objectives of the ruling.
11.2	Implementation	CFR 21 Part 11 refers to systems. It is the end user's responsibility to ensure that a system is compliant.
11.3	Definitions	No comments. BIC accepts the definitions.
11.10	Closed Systems	<i>BI-PSD21</i> always runs as a closed system in the sense that access to a <i>BI-PSD21</i> system must be via a specific <i>BI-PSD21</i> user interface which has access controls. <i>BI-PSD21</i> can export information to third party applications which might be classed as open.
	a. Validation	Each record saved to the <i>BI-PSD21</i> database includes a label to detect alterations to the data. When data is retrieved this label is verified and errors are reported as necessary.
	b	The <i>BI-PSD21</i> database stores results in human readable form and /or encrypted form.
	c	The data are stored in encrypted form in the database. The database will, by default, be stored in the windows directory. It is the users responsibility to prevent unauthorized access to this directory.
	d	Access to <i>BI-PSD21</i> requires a username and password. All user actions involving changes of parameters after completion of the first sample are enforced. A password is required. Passwords are aged.
	e	All user actions involving a change of parameters after completion of the first sample are added to an audit log. Each entry is time stamped, has the user ID, has a description of the user's action, and is labelled to detect alteration.
	f	Where possible this is implemented.
	g	Users are assigned access to various functions. User

Section	Ruling	Comment
		actions are password protected.
	h	All data input is validated for choice and range.
	i	This is an end user activity.
	j	This is an end user activity.
	k	BIC follow a change control procedure as part of the <b>BI-PSD21</b> life cycle.
11.30	Controls for Open Systems	<b>BI-PSD21</b> always runs as a closed system in the sense that access to a <b>BI-PSD21</b> system must be via a specific <b>BI-PSD21</b> user interface which has access controls. <b>BI-PSD21</b> can export information to third party applications which might be classed as open.
11.50	Signature Manifestations	<b>BI-PSD21</b> signatures have the described features. All logs are human readable and alteration protected.
11.70	Signature / Record Linking	All signed records include the signature as part of the record.
11.100	General Requirements	<b>BI-PSD21</b> ensures all current user ID's are unique. The management of User ID's is the responsibility of the end user.
11.200	Electronic Signatures and Controls	To gain access and to be able to sign an action, a user must use a valid username and password to log on. While logged on the user need only supply a password to sign actions.
11.300	Controls for Identification code/passwords	
	a	Only unique user ID's are allowed.
	b	Password ageing ensures passwords must be changed regularly. Any new password cannot be the same as the previous password.
	c	End user responsibility.
	d	Failed login attempts are logged. After a given number of failed attempts, the user interface will close.
	e	This is an end user activity.