

Advanced Security Functions with 21 CFR Part 11 compliance



Bulletin 04L41B01-02E

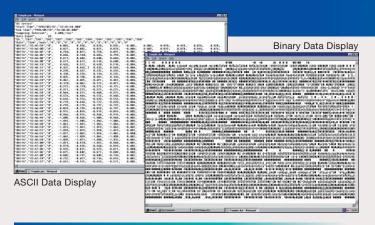
www.daqstation.com











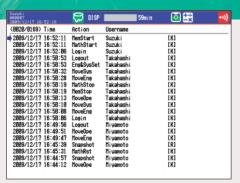
### Secure electronic records

Measured data, settings, and operation logs, are saved to a single encoded binary file. Encoded data in binary format offers a high level of security because it cannot be opened in most text editors. Also, if by chance the data were tampered with or part of the data was damaged, it would be discovered when playing back the data on the DAQSTANDARD software.



### Controlled system access

Up to five system administrators and up to ninety general users can be registered. System administrators register the users and set up individual user login modes, making it possible to limit access to functions on a per-user basis. User name, user ID, password, and password expiration can be assigned for each user. Also, user names and passwords can be centrally controlled from a server on the network.



Operation Log Screen

### Audit trail function

Settings changes and operation logs are automatically recorded and saved to a file along with measured data. This recorded logs of settings changes and operations can be viewed on the DX main unit or DAQSTANDARD software.



Sign Record

### Electronic signature (record signing) function

Once measured data is loaded and displayed on the DX recorder or DAQSTANDARD software, an electronic signature can be added. Three levels of signature are available: operator, supervisor, and quality control. The signature, along with information such as pass/fail determination and comments, can be attached to the record and saved.

# 21 CFR Part 11 Compliance with the advanced security function option (/AS1)

New Advanced Security option /AS1 for the DXAdvanced R4 provides compliance with FDA regulation 21 CFR Part 11.

This option supports a multitude of pharmaceutical, biotech, aerospace, and other industry applications that require rigorous security, data management, and electronic signature functions.

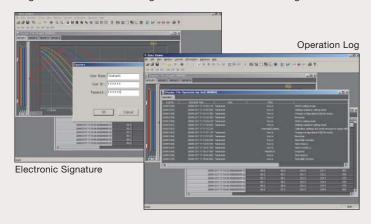


## DAQSTANDARD Software

Updated with Part 11 compliance,
DAQSTANDARD software (included at
no charge) provides configuration,
record viewing, audit trail, and electronic
signature functions. It provides
full support of all previous
DAQSTATION models including DX-P.

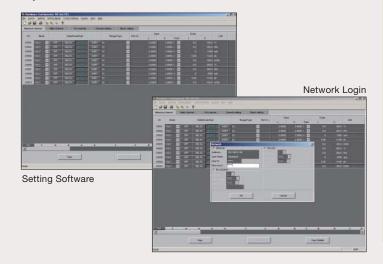
### Viewer software

This software enables you to display data files recorded on the DX in a variety of formats including waveform and digital display. Not limited to measured data, the software can also display and print alarm and message lists, or operation logs. Once you have checked measured data, you can electronically sign the data by entering a user name, ID, and password. If the data was signed previously, you can confirm the signature status and then sign it under a different level of signature.



### Settings software

Various DX settings can be entered via an external media, or via communications (the latter requires DX recorder system administrator privileges). Settings can be printed in a table format to support DX system validation.



## Validation documentation

Validation documentation (sold separately) is a validation protocol template that simplifies DX and DAQSTANDARD system validation. The document is provided as an MS Word file on CD-ROM for easy editing. \*

 $^{\star}$  The validation and document verification are the customer's responsibility.



### **MODEL AND SUFFIX CODES**

Model code	Suffix code		Optional code	Description
DX1002				2ch, 125ms (Fast sampling mode: 25ms)
DX1004				4ch, 125ms (Fast sampling mode: 25ms)
DX1006			6ch, 1s (Fast sampling mode: 125ms)	
DX1012				12ch, 1s (Fast sampling mode: 125ms)
Internal memory	-3			400MB
External media	-4			CF card (with media)
Display language		-2		English, degF, DST(summer/winter time)
Options			/A1	Alarm output 2 points *1
			/A2	Alarm output 4 points *1
			/A3	Alarm output 6 points *1 *2
			/C2	RS-232 interface *3
			/C3	RS-422-A/485 interface *3
			/F1	FAIL/Status output *2
			/H2	Clamped input terminal (detachable)
			/H5	Desktop type (for /P1 model, without power code, screw type power terminal) *4
			/H5[]	Desktop type *5
			/M1	Mathematical functions
			/N1	Cu10,Cu25 RTD input/3 leg isolated RTD
		/N2	3 leg isolated RTD *6	
			/N3	Extended input type (PR40-20, Pt50, etc.)
			/P1	24VDC/AC power supply
			/R1	Remote control
			/TPS2	24VDC transmitter power supply (2 loops) *7
			/TPS4	24VDC transmitter power supply (4 loops) *8
			/KB1	Easy text entry (with input terminal) *9 *10
			/KB2	Easy text entry (without input terminal) *9
			/USB1	USB interface
			/PM1	Pulse input (including remote control and mathematical functions) *11
			/CC1	Calibration correction function
			/BT2	Multi-batch functions *12
			/CP1	PROFIBUS-DP functions *3
			/AS1	Advanced security functions (Part 11 compliant)

- 1 /A1, /A2 and /A3 cannot be specified together.
  2 /A3 and /F1 cannot be specified together.
  3 /C2, /C3 and AF1 cannot be specified together.
  4 in case that 24 VDC/AC power supply (P1) and desktop type are specified together, /H5 must be considered. /P1 and /H5[] cannot be specified together.

- together.

  \*5 /H5[]

  -D: Power cord UL, CSA st'd

  -F: Power cord VDE st'd

  -R: Power cord SAA st'd

  -J: Power cord BS st'd

  -H: Power cord GB st'd

- \*6 /N2 can be specified for only DX1006 and DX1012.

  \*7 In case that /TPS2 is specified /TPS4, /A2, /A3 or /F1 cannot be specified together.

  \*8 In case that /TPS4 is specified, /TPS2, /A1, /A2, /A3 or /F1 cannot be specified together.

  \*9 /KS1 and /KS2 cannot be specified together.

  \*10 In case that /KS1 is specified, remote input terminal (438227) is included.

  \*11 In case that /FM1 is specified, /A3, /M1, /R1, /TPS2 or /TPS4 cannot be specified. And combination of /A2/F1 cannot be specified together.
- together. \*12 /BT2 can be specified for only DX1006, DX1012.

### **APPLICATION SOFTWARE**

Model code	Description	OS	
DXA120	DAQSTANDARD	Windows 2000/XP/Vista	
DXA170	DAQStudio	Windows XP/Vista	

### **ACCESORIES**

Product	Model code (part number)	Specification		
	415920	250Ω±0.1%		
Shunt resister (for screw input terminal)	415921	100Ω±0.1%		
(101 Screw Input terrimal)	415922	10Ω±0.1%		
	438920	250Ω±0.1%		
Shunt resister (for clamped input terminal)	438921	100Ω±0.1%		
(for clamped input terminal)	438922	10Ω±0.1%		
CF card adapter	772090	=		
CF card	772093	512MB		
CF card	772094	1GB		
Mounting bracket	B9900BX	=		
Door lock key	B8706FX	=		
Remote control terminal	438227	For /KB1, /KB2 option		
Validation document	438230	For /AS1 option		

### DX2000

Model code	Suffix code	Optional code	Description
DX2004			4ch, 125ms(Fast sampling mode: 25ms)
DX2008			8ch, 125ms(Fast sampling mode: 25ms)
DX2010			10ch, 1s(Fast sampling mode: 125ms)
DX2020			20ch, 1s(Fast sampling mode: 125ms)
DX2030			30ch, 1s(Fast sampling mode: 125ms)
DX2040			40ch, 1s(Fast sampling mode: 125ms)
DX2048			48ch, 1s(Fast sampling mode: 125ms)
Internal memory	-3		400MB
External media -4			CF card (with media)
Display language	-2		English, degF, DST(summer/winter time)
Options		/A1	Alarm output 2 points *1
		/A2	Alarm output 4 points *1
		/A3	Alarm output 6 points *1
		/A4	Alarm output 12 points *1
		/A5	Alarm output 24 points *1 *2
		/C2	RS-232 interface *3
		/C3	RS-422-A/485 interface *3
		/D5	VGA output
		/F1	FAIL/Status output *2 *4
		/F2	FAIL + Alarm output 22 points *1 *4
		/H2	Clamped input terminal (detachable)
		/H5	Desktop type (for /P1 model, without power code, screw type power terminal) *5
		/H5[]	Desktop type *6
		/M1	Mathematical functions
		/N1	Cu10,Cu25 RTD input/3 leg isolated RTD
		/N2	3 leg isolated RTD *7
		/N3	Extended input type (PR40-20, Pt50, etc.)
		/P1	24VDC/AC power supply
		/R1	Remote control
		/TPS4	24VDC transmitter power supply (4 loops) *8
		/TPS8	24VDC transmitter power supply (8 loops) *9
		/KB1	Easy text entry (with input terminal) *10 *11
		/KB2	Easy text entry (without input terminal) *10
		/USB1	USB interface
		/PM1	Pulse input (including remote control and mathematical functions) *12
		/CC1	Calibration correction function
		/MC1	External input function *13
		/BT2	Multi-batch functions *14
		/CP1	PROFIBUS-DP functions *3
		/AS1	Advanced security functions (Part 11 compliant)
1 /A1, /A2, /A3, /A4	/AF /F0	at he appointed	*7 /N2 can be specified for only DX2010, DX2020.

- \*1 /A1, /A2, /A3, /A4, /A5, /F2 cannot be specified
- together.

  2 /A5 and /F1 cannot be specified together.

  2 /A5 and /F1 cannot be specified together.

  3 /C2, /C3 and /CP1 cannot be specified together.

  4 /F1 and /F2 cannot be specified together.

  5 In case that 24 VDC/AC power supply (/P1) and desktop type are specified together. /H5 must be specified. /P1 and /H5[] cannot be specified together.
- together.

  \*6 /H5[]

  -D: Power cord UL, CSA st'd

  -F: Power cord VDE st'd

  -R: Power cord SAA st'd

  -J: Power cord SA st'd

  -J: Power cord BS st'd

  -H: Power cord BB st'd
- \*7 /N2 can be specified for only DX2010, DX2020, DX2030, DX2040 and DX2048.

  \*8 /TPS4, /TPS8, /A5 and /F2 cannot be specified

- 18 /TPS4, /TPS4, /A5 and /F2 cannot be specified together.
  19 In case that /TPS8 is specified, combination of /A4/F1 cannot be specified together.
  10 /KB1 and /KB2 cannot be specified together.
  11 In case that /KB1 is specified, remote input terminal (438227) is included.
  12 In case that /PM1 is specified, /A5, /F2, /M1 and /R1 cannot be specified. And combination of /A2/F1 and combination of /A4/TPS8 cannot be specified together.
- specified together.

  13 /MC1 can be specified for only DX2010, DX2020, DX2030, DX2040 and DX2048.

  14 /BT2 can be specified for only DX2010, DX2020, DX2030, DX2040, DX2048.

### NOTICE -

- Before operating the product, read the instruction manual thoroughly for proper and safe operation.
- If this product is for use with a system requiring safeguards that directly involve personnel safety, please contact the Yokogawa sales offices.

Daqstation and DXAdvanced are registered trademark of Yokogawa Electric Corporation. Microsoft, MS, and Windows are registered trademarks or trademarks of Microsoft Corporation in the United States and other countries.

PROFIBUS-DP is a registered trademarks of PROFIBUS User Organization. Other company names and product names appearing in this document are registered trademarks or trademarks of their respective holders.









VigilantPlant is Yokogawa's automation concept for safe, reliable, and profitable plant operations. VigilantPlant aims to enable an ongoing state of Operational Excellence where plant personnel are watchful and attentive, well-informed, and ready to take actions that optimize plant and business performance.

### YOKOGAWA ELECTRIC CORPORATION

Network Solutions Business Div./Phone: (81)-422-52-7179, Fax: (81)-422-52-6619 E-mail: ns@cs.jp.yokogawa.com

YOKOGAWA CORPORATION OF AMERICA

YOKOGAWA EUROPE B.V. YOKOGAWA ENGINEERING ASIA PTE. LTD. Phone: 800-258-2552, Fax: (1)-770-254-0928 Phone: (31)-88-4641000, Fax: (31)-88-4641111 Phone: (65)-62419933, Fax: (65)-62412606

NetSOL Online Sign up for our free e-mail newsletter www.yokogawa.com/ns/

Vig-RS-4E Printed in Japan, 002(KP) [Ed: 01/b]

