



Digitized Automation for a Changing World

Delta HMI DOP-300 Series FDA 21 CFR Part 11 Compliant



For the Medical, Pharmaceutical, and Food & Beverages Industries

The Delta HMI DOP-300 Series complies with FDA 21 CFR Part 11 and is designed to ensure data accuracy, integrity, and traceability. With the FDA 21 CFR Part 11 compliance, the DOP-300 is an ideal solution for machines in the medical, pharmaceutical, and food & beverages industries

To comply with 21 CFR, the DOP-300 Series primarily addresses the following aspects

FDA 21 CFR Part 11 is a regulation issued by the U.S. Food and Drug Administration (FDA). Its core values are enhancing compliance, security, data integrity, and operational efficiency. It enables companies to meet regulatory requirements while increasing automation in production and management processes, ultimately strengthening market competitiveness.



Compliance with Electronic Records

Ensures that electronic records are generated, stored, and managed in a manner that maintains the integrity and reliability of the records.



Electronic Signatures (Secure Account Management)

The system administrator has settings access to create new accounts, lockout users, and de-authorize them, but no one has access to user passwords. Changes can be logged while the runtime is not operating.



System Security

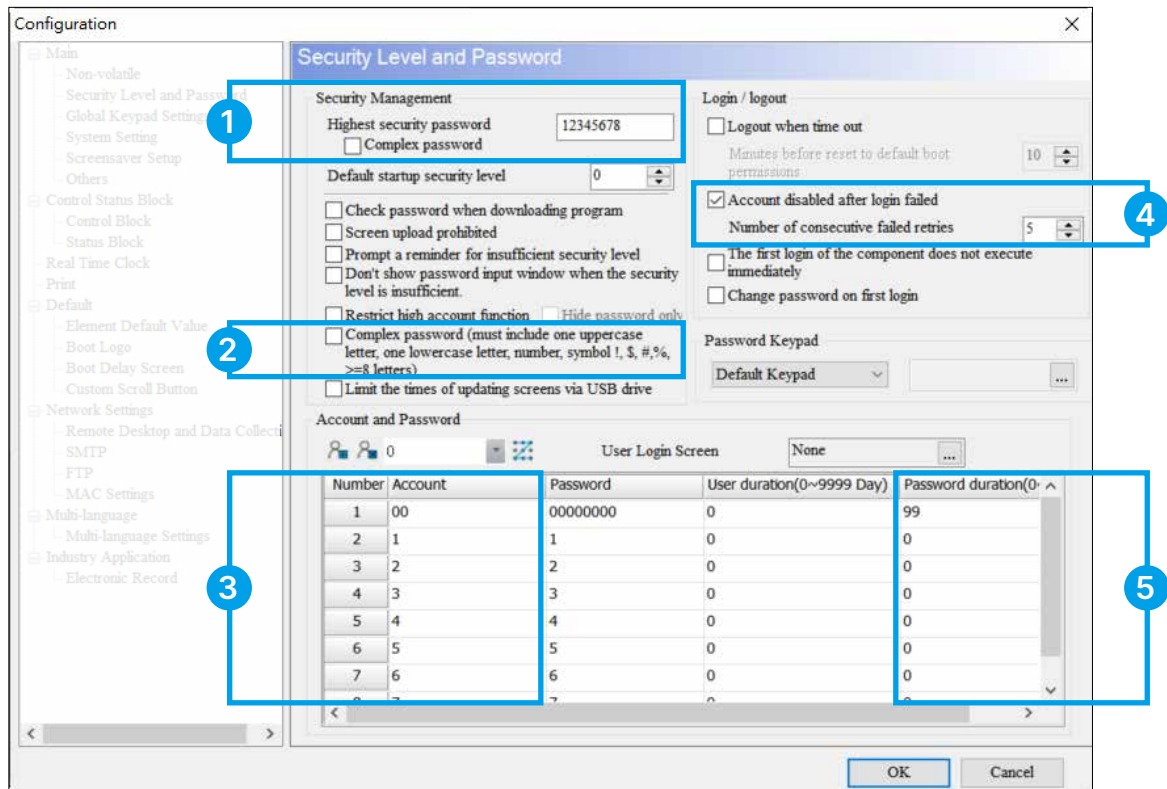
Ensures the systems have appropriate security controls, such as user authentication and access control, to protect records from unauthorized access or alteration.

*Please refer to the DOP-300 Series User Manual for more detailed setup and product information.



FDA 21 CFR Compliant Functions

Account Management



1 Security password

The password length should be at least 8 digits

2 Complex passwords

At least one uppercase and lowercase letter, number, and symbol

3 Unique user account

Unique account to ensure data security

4 Limitation of password attempts

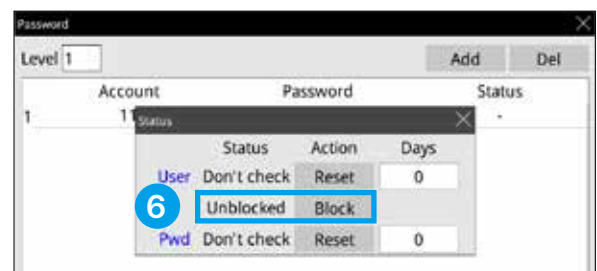
Set the number of consecutive failed password entries before the account is disabled

5 Password duration

The expiration date of the user account can be pre-set, and the system deletes it after expiration

6 Block / unblock

Specific user accounts can be blocked but still exist in the system



FDA 21 CFR Compliant Functions

Operation

7 User actions are recorded with timestamps to create an audit trail

The record includes the following information:

- User creation
- User login/logout
- User block/unblock by administrator
- Login attempt
- Old/new value after data change
- Timestamp

Time	User	Level	Screen	Description	Action	Address	Pre Value
00:25		0			HMI Startup		
01:14		0			Login		
01:21	66	6			Incorrect Passwo		
01:26	66	6			Incorrect Passwo		
01:33	66	6			Account Not Four		
01:34		0	ScreenPassword Table	Set Passwd			
01:42	66	6	ScreenNumeric Entry_0	(Set Val		\$1	0

Data Backup

8 The DOP-300 Series supports the following protocols for data sharing with SCADA, MES, and ERP systems: FTP, USB/SD, and OPC UA

Path: [DIAScreen] → [Configuration] → [Network Setting] → [FTP]

The screenshot shows the 'Configuration' window with a tree view on the left and a 'FTP' settings panel on the right. The tree view includes categories like Main, Control Status Block, Real Time Clock, Print, Default, and Network Settings. The 'FTP' panel has tabs for 'FTP Host' and 'FTP File Setting'. Under 'FTP Host', there is a checkbox for 'Enable FTP host function' which is checked. Below this are input fields for 'FTP Host Port' (21), 'Account' (hmi), 'Password' (12345678), 'Root Directory' (USB Disk), and 'Network'. There is also an unchecked checkbox for 'Anonymous'.

Path: [DIAScreen] → [Configuration] → [Main] → [Non-volatile]

Configuration

- Main
 - Non-volatile
 - Security Level and Password
 - Global Keypad Settings
 - System Setting
 - Screensaver Setup
 - Others
- Control Status Block
 - Control Block
 - Status Block
- Real Time Clock
- Print

Non-volatile

Non-volatile data storage

Name	Non-volatile	Storage Location
Alarm	No	USB Disk
Recipe	Yes	USB Disk
History Buffer ID-1	Yes	USB Disk HMI USB Disk USB Disk 2 SD

Path: [DIAScreen] → [IIoT] → [OPC UA Server]

General Project Elements Data Management **IIoT**

OPC UA Server
MQTT Settings
4G Dongle
DIACloud
Notification

Path: [DIAScreen] → [Communication] → [OPC UA Client]

Device Localhost

Link Name Detail

00- EtherLink1	Controller OPC UA Client	Import
----------------	--	--------

FDA 21 CFR Compliant Functions

Electronic Records

9 Historical data, alarms, and operation log reports

The DOP-300 Series generates historical data /operation logs, and sends alarms

History Buffer

History Buffer window showing Buffer Properties and File Output settings. The Buffer Properties section includes Address (10), Read Length (Word) (1), Sample Number (10), and checkboxes for Non-volatile, Auto Stop, Export CSV File, and Enable active bit. The File Output section includes a dropdown for Save in (USB Disk), a dropdown for Insufficient storage space (Stop Log), a spinner for Maximum file size (10 MB), and a spinner for Upper limit setting (10000).

Operation Log

Operation Log Setting window showing Enable checkbox checked, Trigger Address (\$0.0), Save in (USB Disk), Insufficient storage space (Stop Log), Maximum file size (10 MB), and Upper limit setting (10000).

Alarm

Alarm configuration window showing settings for Address, Acknowledge all alarms, Scan Time (seconds), Max Records, Non-volatile Data Storage (USB Disk), Export CSV File (Yes), CSV Field Setting, Exit Screensaver when alarm occurs, Time to enter screen saver again, and Display alarm screen.

10 The storage space will vary based on report generation or the percentage of memory used

When there's too little memory left, the pop-up window is displayed.

The DOP-300 Series storage space can be set through the Configuration tab

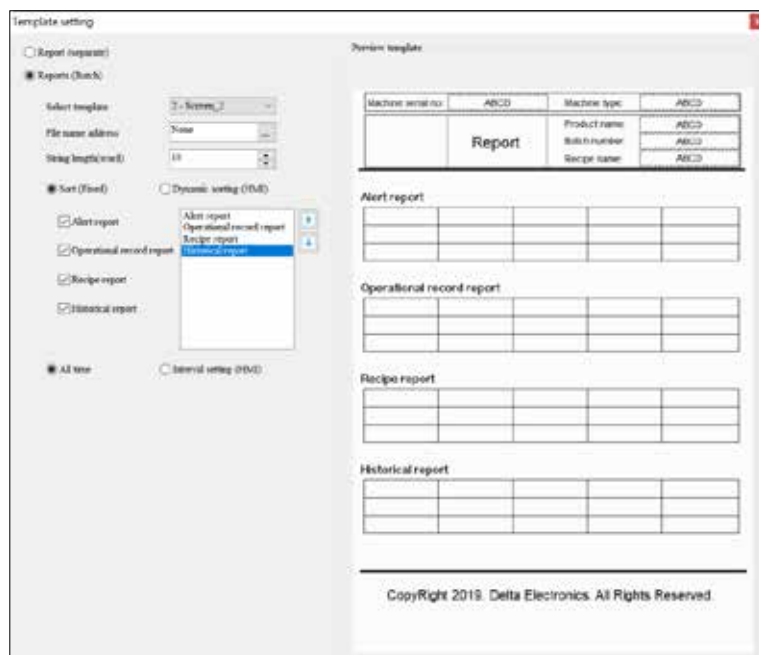
Configuration window showing the Others tab. The Show disk accessing error message section includes checkboxes for Alarm, History Buffer, and Recipe. The Insufficient storage hint screen section includes an Enable checkbox and a table for storage settings.

	Remaining space	Jump to the specified screen
HMI	5 (5~10MB)	None
USB Disk	5	None
USB Disk 2	5	None
SD	5	None

Report Merge & Printing

11 Batch report

The DOP-300 Series consolidates historical data, recipe, alarms, and operation logs into a PDF report



12 Data print-out

Supports 16 printer drivers of different brands (Honeywell, HP, EPSON, ZEBRA, GoDEX, Micro Printer, PDF Writer, and more)



Ordering Information

Product	Dimensions	CPU	RAM	ROM	Ethernet Port	Serial Port	DIACloud	Model	Certificates
HMI DOP-300	7 inches	Dual Core 1.2 GHz	512 MB	512 MB	2	3	Built-in	DOP-3S07S3E2	CE, UL
	10.1 inches							DOP-3S10S3E2	

1. To ensure usage rights, please activate and use it within two years after shipment from Delta, and it will be valid within one year after activation.
2. For more details, please refer to DOP-300 catalog.



Smarter. Greener. Together.

Industrial Automation Headquarters

Taiwan: Delta Electronics, Inc.

Taoyuan Technology Center
No.18, Xinglong Rd., Taoyuan District,
Taoyuan City 330477, Taiwan
TEL: +886-3-362-6301 / FAX: +886-3-371-6301

Asia

China: Delta Electronics (Shanghai) Co., Ltd.

No.182 Minyu Rd., Pudong Shanghai, P.R.C.
Post code : 201209
TEL: +86-21-6872-3988 / FAX: +86-21-6872-3996
Customer Service: 400-820-9595

Japan: Delta Electronics (Japan), Inc.

Industrial Automation Sales Department
4-11-25, Shibaura, Minato-ku, Tokyo 108-0023, Japan
TEL: +81-3-6811-5470 / FAX: +81-3-6811-5802

Korea: Delta Electronics (Korea), Inc.

1511, 219, Gasan Digital 1-Ro., Geumcheon-gu,
Seoul, 08501 South Korea
TEL: +82-2-515-5305 / FAX: +82-2-515-5302

Singapore: Delta Energy Systems (Singapore) Pte Ltd.

4 Kaki Bukit Avenue 1, #05-04, Singapore 417939
TEL: +65-6747-5155 / FAX: +65-6744-9228

India: Delta Electronics (India) Pvt. Ltd.

Plot No.43, Sector 35, HSIIDC Gurgaon,
PIN 122001, Haryana, India
TEL: +91-124-4874900 / FAX: +91-124-4874945

Thailand: Delta Electronics (Thailand) PCL.

909 Soi 9, Moo 4, Bangpoo Industrial Estate (E.P.Z),
Pattana 1 Rd., T.Phraksa, A.Muang,
Samutprakarn 10280, Thailand
TEL: +66-2709-2800 / FAX: +66-2709-2827

Australia: Delta Electronics (Australia) Pty Ltd.

Unit 2, Building A, 18-24 Ricketts Road,
Mount Waverley, Victoria 3149 Australia
Mail: IA.au@deltaww.com
TEL: +61-1300-335-823 / +61-3-9543-3720

Americas

USA: Delta Electronics (Americas) Ltd.

5101 Davis Drive, Research Triangle Park, NC 27709, U.S.A.
TEL: +1-919-767-3813

Brazil: Delta Electronics Brazil Ltd.

Estrada Velha Rio-São Paulo, 5300 Eugênio de
Melo - São José dos Campos CEP: 12247-004 - SP - Brazil
TEL: +55-12-3932-2300 / FAX: +55-12-3932-237

Mexico: Delta Electronics International Mexico S.A. de C.V.

Gustavo Baz No. 309 Edificio E PB 103
Colonia La Loma, CP 54060
Tlalnepantla, Estado de México
TEL: +52-55-3603-9200

EMEA

EMEA Headquarters: Delta Electronics (Netherlands) B.V.

Sales: Sales.IA.EMEA@deltaww.com
Marketing: Marketing.IA.EMEA@deltaww.com
Technical Support: iatechnicalsupport@deltaww.com
Customer Support: Customer-Support@deltaww.com
Service: Service.IA.emea@deltaww.com
TEL: +31(0)40 800 3900

BENELUX: Delta Electronics (Netherlands) B.V.

Automotive Campus 260, 5708 JZ Helmond, The Netherlands
Mail: Sales.IA.Benelux@deltaww.com
TEL: +31(0)40 800 3900

DACH: Delta Electronics (Netherlands) B.V.

Coesterweg 45, D-59494 Soest, Germany
Mail: Sales.IA.DACH@deltaww.com
TEL: +49 2921 987 238

France: Delta Electronics (France) S.A.

ZI du bois Challand 2, 15 rue des Pyrénées,
Lisses, 91090 Evry Cedex, France
Mail: Sales.IA.FR@deltaww.com
TEL: +33(0)1 69 77 82 60

Iberia: Delta Electronics Solutions (Spain) S.L.U

Ctra. De Villaverde a Vallecas, 265 1º Dcha Ed.
Hormigueras - P.I. de Vallecas 28031 Madrid
TEL: +34(0)91 223 74 20
Carrer Llacuna 166, 08018 Barcelona, Spain
Mail: Sales.IA.Iberia@deltaww.com

Italy: Delta Electronics (Italy) S.r.l.

Via Meda 2-22060 Novedrate(CO)
Piazza Grazioli 18 00186 Roma Italy
Mail: Sales.IA.Italy@deltaww.com
TEL: +39 039 8900365

Turkey: Delta Greentech Elektronik San. Ltd. Sti. (Turkey)

Şerifali Mah. Hendem Cad. Kule Sok. No:16-A
34775 Ümraniye - İstanbul
Mail: Sales.IA.Turkey@deltaww.com
TEL: + 90 216 499 9910

MEA: Eltek Dubai (Eltek MEA DMCC)

OFFICE 2504, 25th Floor, Saba Tower 1,
Jumeirah Lakes Towers, Dubai, UAE
Mail: Sales.IA.MEA@deltaww.com
TEL: +971(0)4 2690148

*We reserve the right to change the information in this catalogue without prior notice.