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

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

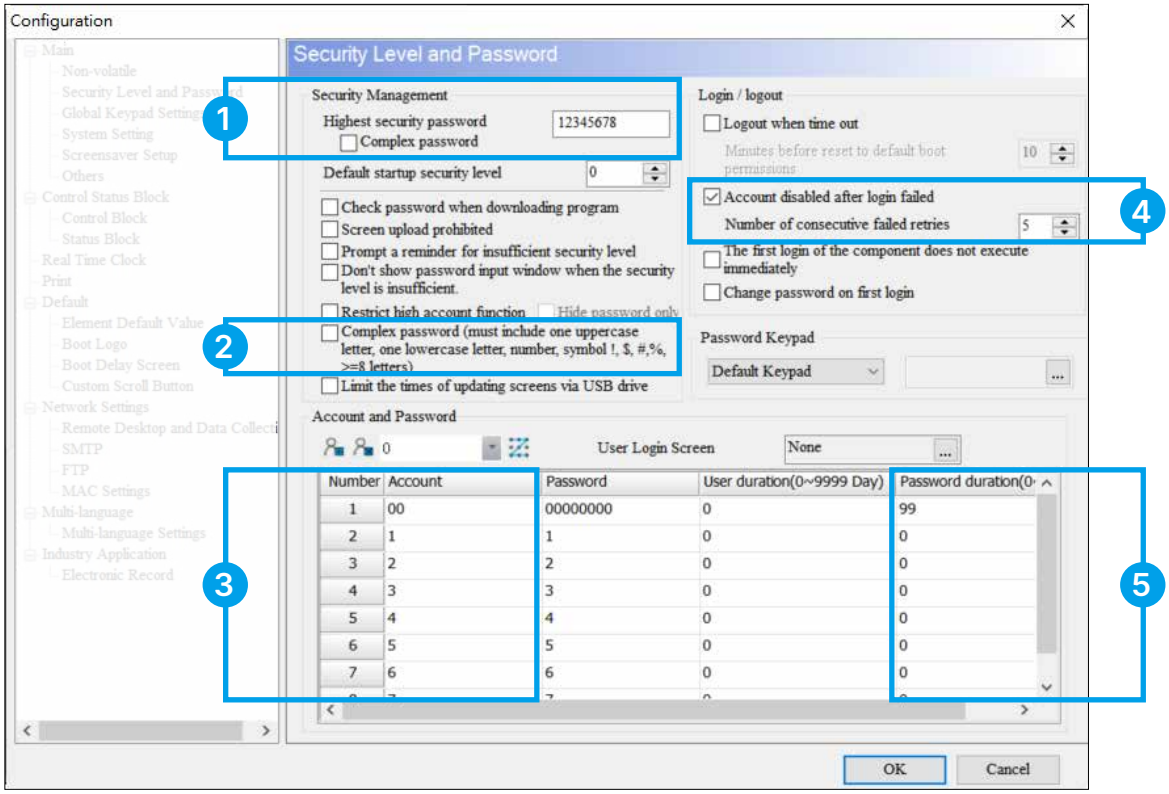
Ensures the systems have appropriate security controls, such as user authentication and access control, to protect records from unauthorized access or alteration.

- The Delta HMI DOP-300 Series complies with the FDA 21 CFR and ensures data accuracy, integrity, and traceability. The following pages briefly introduce how the DOP-300 Series supports the compliance with 21 CFR.

  ※ 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

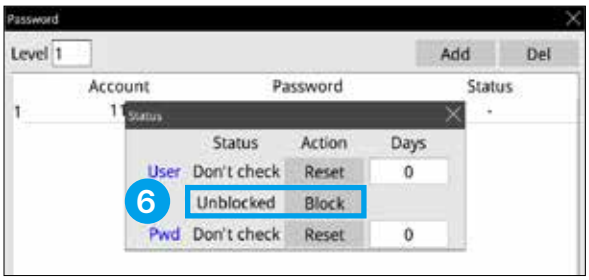
2 Complex passwords
At least one uppercase and lowercase letter, number, and symbol

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:

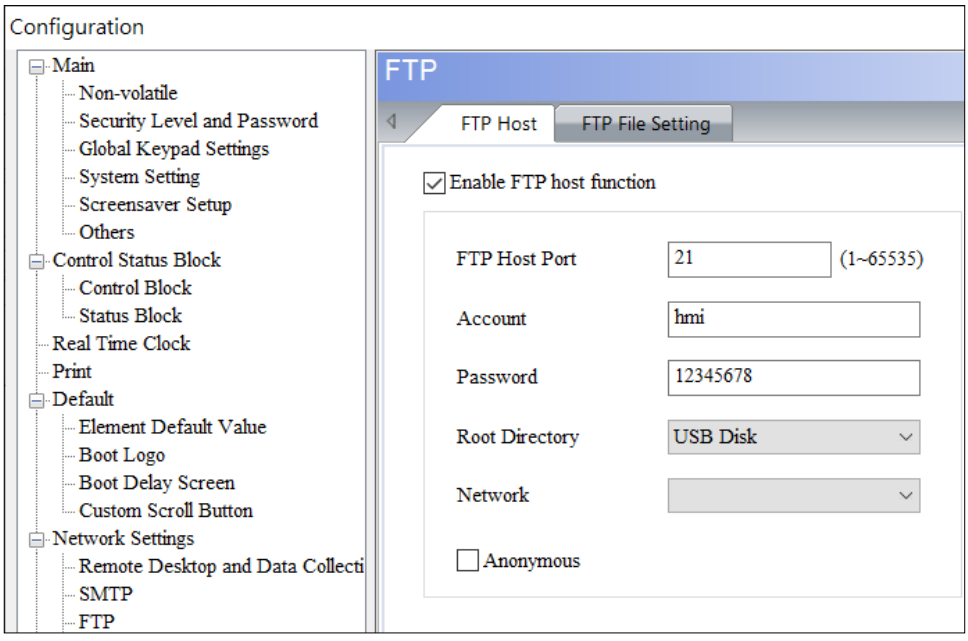
- User creation
- User login / logout
- User block / unblock by administrator
- Login attempt
- Old / new value after data change
- Timestamp

Time	User	Level	Screer	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	Screen	Password Table S	Set Passwd		
01:42	66	6	Screen	Numeric Entry_0(	Set Val	$1	0

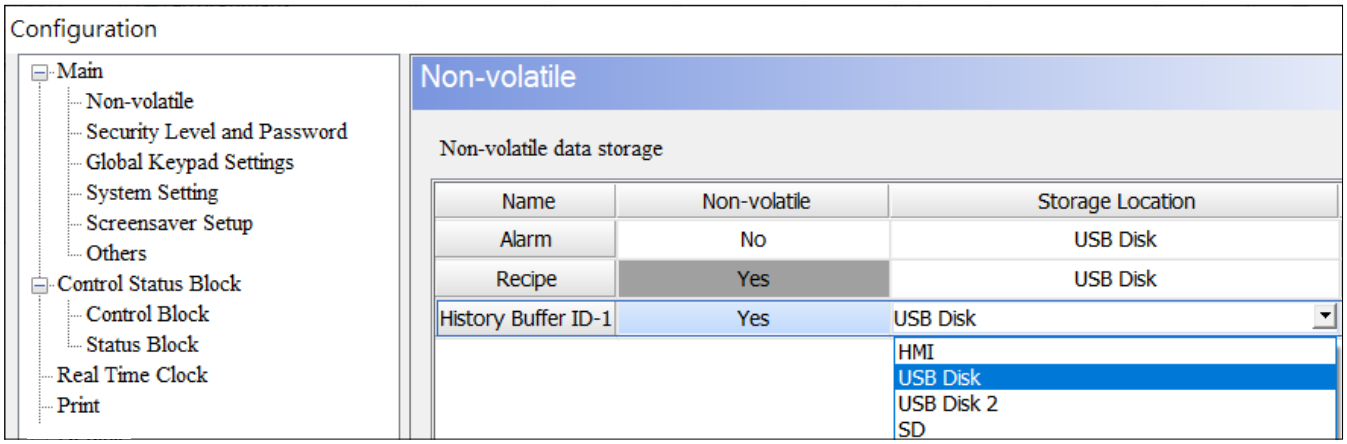
Data Backup

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

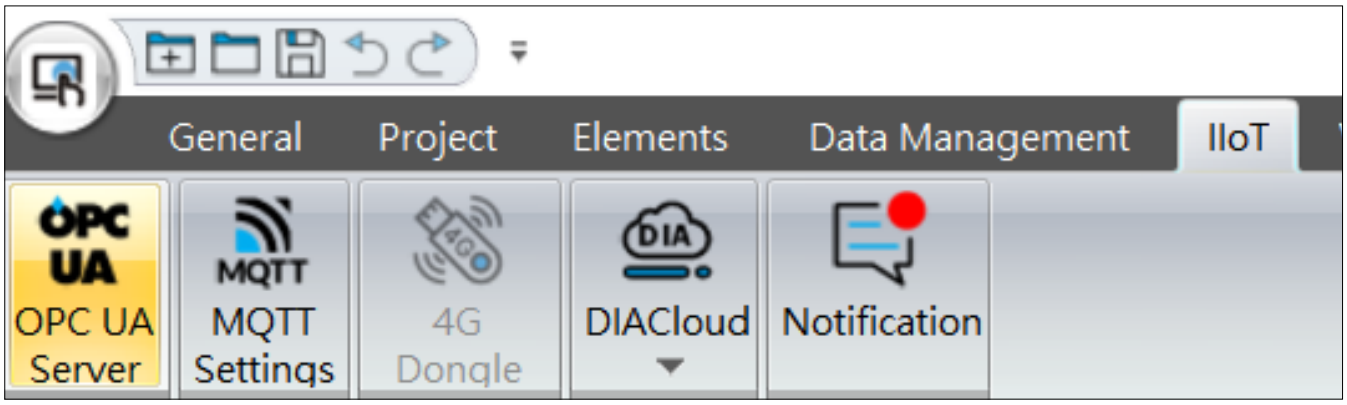
Path:【DIAScreen】→【Configuration】→【Network Setting】→【FTP】



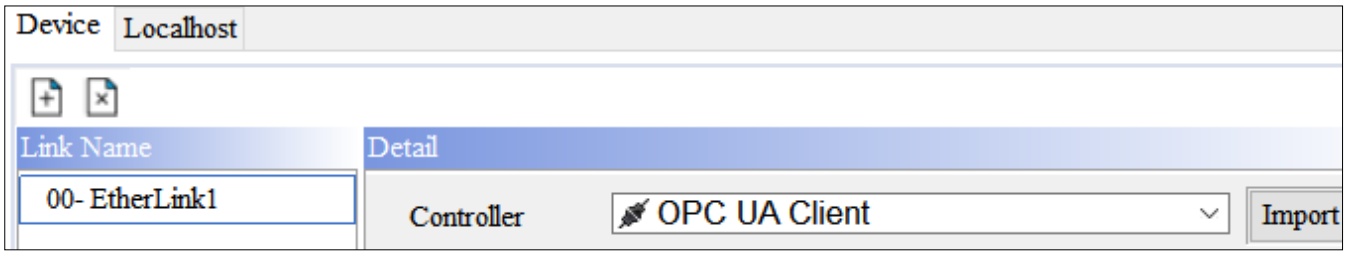
Path:【DIAScreen】→【Configuration】→【Main】→【Non-volatile】



Path:【DIAScreen】→【IIoT】→【OPC UA Server】



Path:【DIAScreen】→【Communication】→【OPC UA Client】



FDA 21 CFR Compliant Functions

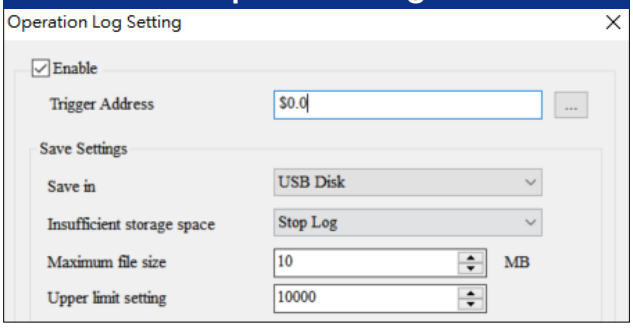
Electronic Records

9 Historical data, alarms, and operation log reports

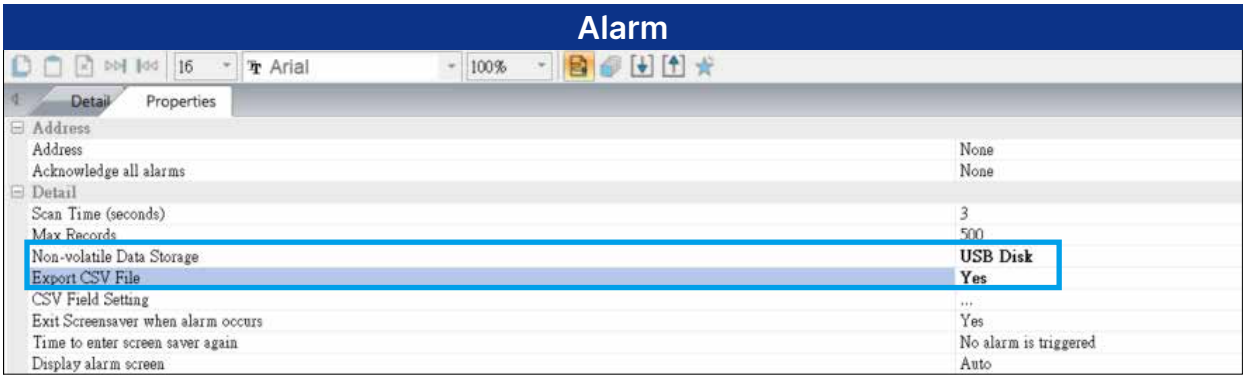
The DOP-300 Series generates historical data / operation logs, and sends alarms

History Buffer

Operation Log

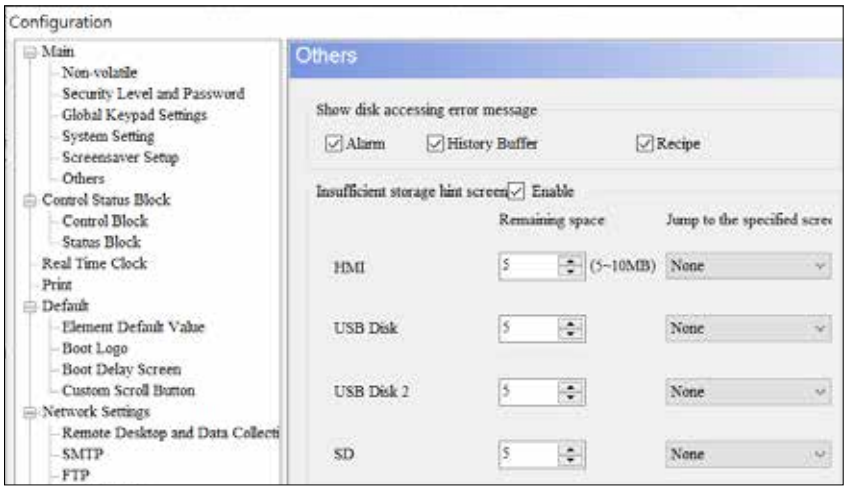


Alarm



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

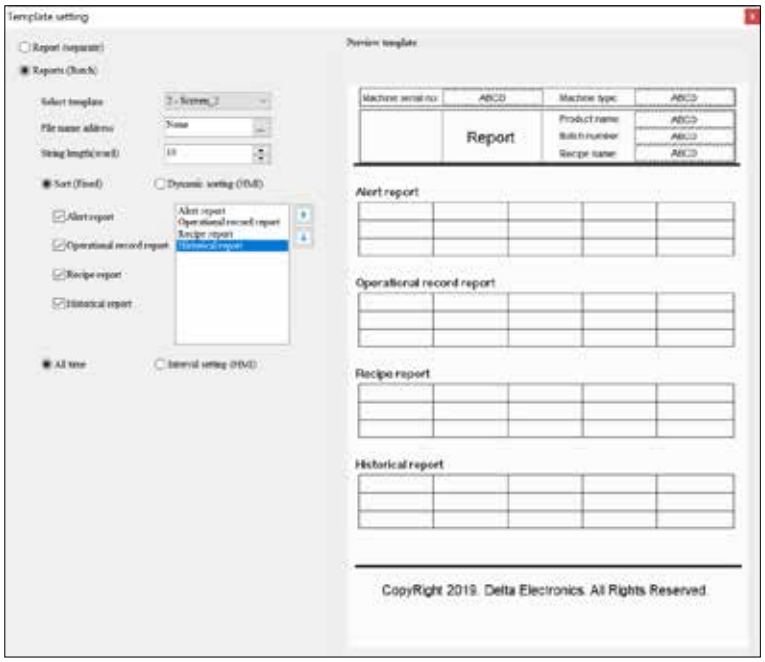
When there's too little memory left, the pop-up window is displayed.
The DOP-300 Series storage space can be set through the Configuration tab



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	Dimensiions	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
2-1-14 Shibadaimon, Minato-ku
Tokyo, Japan 105-0012
TEL: +81-3-5733-1155 / FAX: +81-3-5733-1255

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

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