

INSTECH JM.S

FDA 21 CFR Part 11

March 8, 2021

Instech JM.S Development and Function

Instech JM.S includes a set of functions for responding to the requirements specified in FDA 21 CFR Part 11.

The standard is intended to provide a solution for securely handling electronic records and electronic signatures in industrial applications.





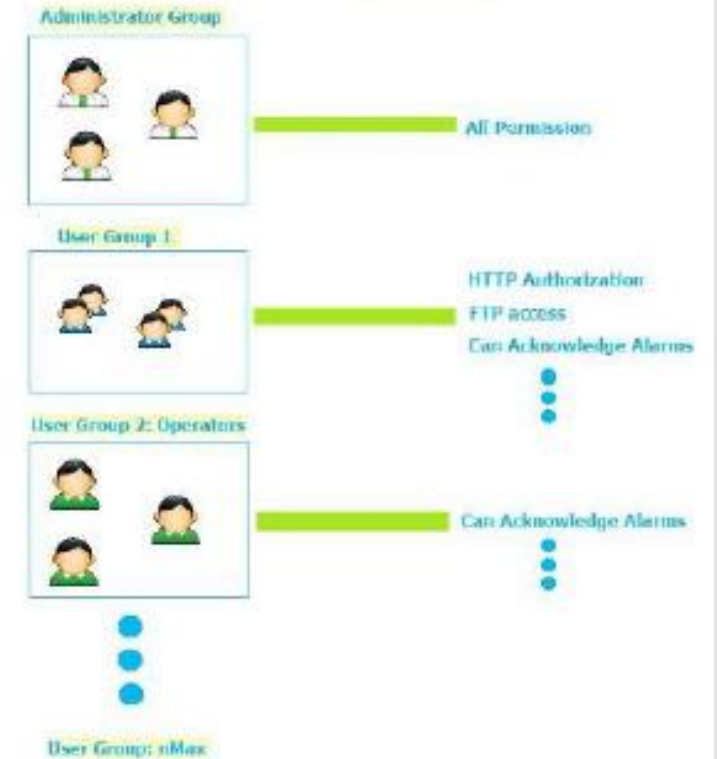
User Management Security



User Management

User Groups and Users

- Instech JM.S provides customizable user group dynamics
- You can restrict access to various widgets and operations by configuring users, user groups and assigning specific authorizations to each group
- **Max User Groups = 50**
- **Max Users = 500**
- Each user must be member of one and only one group. Each group has specific authorizations and permissions.
- By organizing permissions and groups you can define the security options of a project



User Management

User Management Parameters

Name	Default User	Inactive	Group	Password	Comments	Exception	Change Initial Password
admin	<input type="checkbox"/>	<input type="checkbox"/>	admin	*****	admin user	<input checked="" type="checkbox"/>	false
user1	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Default	*****	user1	<input checked="" type="checkbox"/>	false
SUP	<input type="checkbox"/>	<input type="checkbox"/>	Supervisor	*****	SUP@123	<input type="checkbox"/>	false
MAN	<input type="checkbox"/>	<input type="checkbox"/>	Manager	*****	MAN@123	<input type="checkbox"/>	false
OPE	<input type="checkbox"/>	<input type="checkbox"/>	Operator	*****	OPE@123	<input type="checkbox"/>	false
user2	<input type="checkbox"/>	<input type="checkbox"/>	unauthorized	*****		<input type="checkbox"/>	false

Common Parameters

Parameters common to all users

- Force to change initial password
- Force log off time (min)
- Minimum Password Length (Char)
- Password must contain special characters
- Password must contain numbers
- Password must contain lower case and upper case
- The last three passwords cannot be reuse
- Number of weeks before force a password change
- Show warnings before password expired (day)

OK Cancel

Parameter	Description
Name	Unique User name
Password	User password. Note that for security reasons the password will never be displayed. Passwords are encrypted and cannot be retrieved not even for specialized technicians
Change Initial Password	User is forced to change his password at first log in
Logoff / Auto log out time (minutes)	Minutes of inactivity after which the user is logged off. Set to 0 to disable
Password minimum length	Minimum length of password
Must contain special characters	Password must contain at least one special character
Must contain numbers	Password must contain at least one numeric digit
Must contain lower case and upper case	Password must contain lower case and upper case
Password cannot be reused	The new password must be different from the last 3 used passwords
Password aging (weeks)	Number of weeks before forcing a password change (1/52 weeks)
Warning (days)	Show a warning message before password expires (1/30 days)

User Management

Managing User at Runtime

Edit User screen

User name: Inactive

Password: Show password

Group:

Comments:

Password must contain number:

Password must contain special:

User must change his initial password:

Inactivity logoff time: min

User Management

Managing User at Runtime

Action for all user

User management macros

User management macros that could be use from any user

Login / Switch User

Logout

Change Password

This action should be set as per authority level/requirements

User management macros that could be used from administrator only

Reset Password

Add User

Edit User

Export User

Failed logging attempts are logged to audit trail. User is not blocked

Inactive User Option is available in Edit User action



Alarm

Active Alarms and History

Alarm with operator acknowledgement

Operator must acknowledge alarm once trigger

Active Alarms - Acknowledge

Select	Name	State	Value	Time	Description	Severity
<input checked="" type="checkbox"/>	Alarm1	Triggered Not Acked	1	05/14/2020 - 08:30:44 ...	emg pressed	1-low

Check/Uncheck All **Ack**

Active Alarms and History

Alarm History View

Log and display alarm buffer

Alarms History Table

From: 15/05/20 - 16:54:24

To: 15/05/20 - 16:59:24

Duration: 5 Mins

Refresh

Column Filter:

Name

Timestamp	Name	State	Value	Description
15/05/20 - 16:55:09	Alarm1	Triggered Not Acked	1	emg pressed
15/05/20 - 16:55:30	Alarm1	Not Triggered Not Acked	0	emg pressed
15/05/20 - 16:55:34	Alarm1	Not Triggered	0	emg pressed
15/05/20 - 16:55:37	Alarm1	Triggered Not Acked	1	emg pressed
15/05/20 - 16:55:39	Alarm1	Triggered Acked	1	emg pressed

Backward

Forward

Alarm Limitations

- Depending on HMI model

Alarm	HMI	4000 alarm can be defined
	PC Runtime	10,000 alarm can be defined
	Max History	10,000 event/ records can be stored



Audit



Audit Trail

The Audit trail/record contains information of the action executed and the user that performed them along with time stamp

Tags

Tags				
Tag	Audit	Signature	Audit Buffer	Comment
Tag1	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	AuditTrail	

Alarms

Alarms				
Alarm	Audit	Signature	Audit Buffer	Comment
Alarm1	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	AuditTrail	

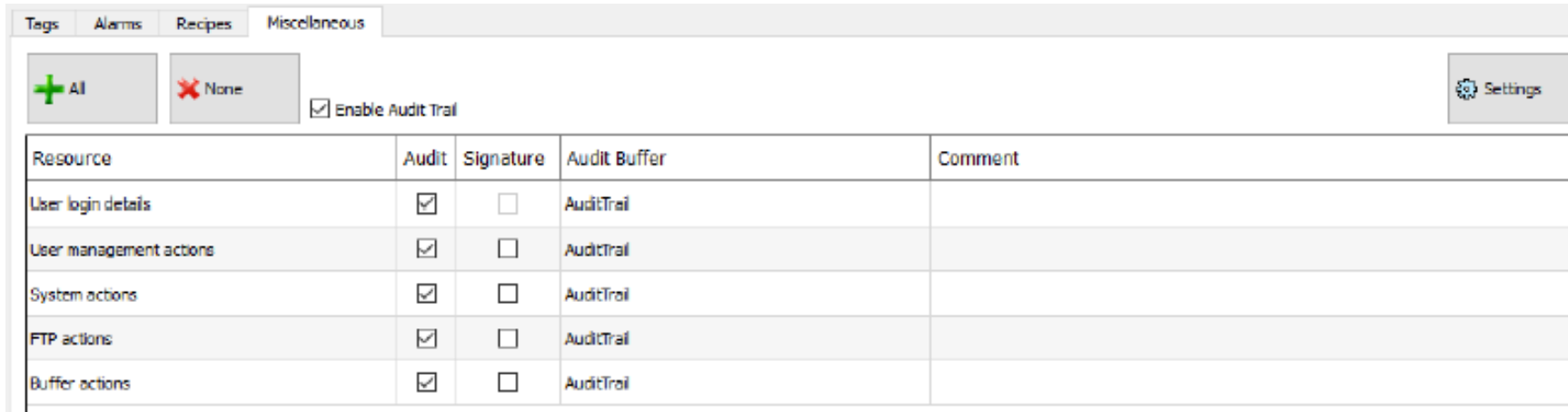
Recipe

Recipe				
Recipe	Audit	Signature	Audit Buffer	Comment
Redpe0	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	AuditTrail	

Audit Trail

The Audit trail/record contains information of the action executed and the user that performed them along with time stamp

Misc.



Resource	Audit	Signature	Audit Buffer	Comment
User login details	<input checked="" type="checkbox"/>	<input type="checkbox"/>	AuditTrail	
User management actions	<input checked="" type="checkbox"/>	<input type="checkbox"/>	AuditTrail	
System actions	<input checked="" type="checkbox"/>	<input type="checkbox"/>	AuditTrail	
FTP actions	<input checked="" type="checkbox"/>	<input type="checkbox"/>	AuditTrail	
Buffer actions	<input checked="" type="checkbox"/>	<input type="checkbox"/>	AuditTrail	

Audit Trail

Electronic Signature

The screenshot shows a software interface with tabs for 'Tags', 'Alarms', 'Recipes', and 'Miscellaneous'. Below the tabs are buttons for '+ All' and '- None', and a checkbox labeled 'Enable Audit Trail' which is checked. A table below contains the following data:

Tag	Audit	Signature	Audit Buffer	Comment
Tag1	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	AuditTrail	

A 'Settings' button is located in the top right corner of the interface.

The user password is required before allowing the resource to be modified by the user

The dialog box has a blue title bar that says 'Confirm your password'. It contains a 'Password:' label above a text input field with masked characters. Below that is a 'Comment:' label above a larger text area containing the text: 'This is a short comment that explains why I am doing this change'. At the bottom are 'Ok' and 'Cancel' buttons.

The dialog box has a title bar that says 'Settings'. It contains a label 'Signature password validity (Sec):' next to a text input field containing the number '10'. At the bottom are 'Ok' and 'Cancel' buttons.

Signature Validity (sec)

- Password will be not required again for the next 10 Sec.
- The validity time can be modified from the Settings dialog.

Audit Trail

Audit view on screen

Audit View

From: 15/05/2020 - 16:28:26
To: 15/05/2020 - 16:58:26
Duration: 30 Mins

Column Filter:

Record ID	Timestamp	UserName	Operation	Information
1	15/05/2020 - 16:54:50	SYSTEM_IDAL	SYSTEM_POWERON	EXORN ON
2	15/05/2020 - 16:54:51	admin	LOGIN	1
3	15/05/2020 - 16:55:09	admin	WRITE_TAG	Tag 1;0;1;comment check
4	15/05/2020 - 16:55:30	admin	WRITE_TAG	Tag 1;1;0;comment 2
5	15/05/2020 - 16:55:34	admin	ACK_ALARM	Alarm 1;comment 2
8	15/05/2020 - 16:55:43	SYSTEM_IDAL	RECIPE_WRITE_TAG	Tag 1;1;0;comment 2
9	15/05/2020 - 16:55:43	admin	DOWNLOAD_RECIPE	Recipe 0;Set 0;0;comment 2
13	15/05/2020 - 16:55:54	admin	UPLOAD_RECIPE	Recipe 0;Set 1;1;comment 2
14	15/05/2020 - 16:56:10	admin	ADD_USER	1;user 1
15	15/05/2020 - 16:56:20	admin	EDIT_USER	1;user 1;inactive
16	15/05/2020 - 16:56:28	admin	DELETE_USER	1;user 1
17	15/05/2020 - 16:56:40	admin	CHANGE_PASSWORD	1
18	15/05/2020 - 16:56:52	admin	LOGOUT	1
19	15/05/2020 - 16:56:52	user 1	LOGIN	Login failed
20	15/05/2020 - 16:57:05	admin	LOGIN	1
23	15/05/2020 - 16:57:28	admin	PRINT_GRAPHICS_REPORT	Graphic Report 1

System Action

Tags

Alarms

Recipe

User Action

Login Attempt Failure

Trend Buffer

Trend View on Screen – Table or Graph

Sample time could be 1 sec or 1/10 seconds

Image of Sample Project:

Trend Table (Log) Batch Name: 20JL17A

From: 28/07/20 - 09:03:52 Duration: 30 Mins Refresh

To: 28/07/20 - 09:33:52

Timestamp	TEMP	HUMI	PRESS	BatchName	UserName
28/07/20 - 09:33:43	24	92	46	20JL17A	user1
28/07/20 - 09:33:44	14	95	47	20JL17A	user1
28/07/20 - 09:33:45	4	98	49	20JL17A	user1
28/07/20 - 09:33:46	0	97	51	20JL17A	user1
28/07/20 - 09:33:47	0	94	52	20JL17A	user1
28/07/20 - 09:33:48	0	91	54	20JL17A	user1
28/07/20 - 09:33:49	0	87	56	20JL17A	user1
28/07/20 - 09:33:50	0	84	57	20JL17A	user1
28/07/20 - 09:33:51	0	81	59	20JL17A	user1
28/07/20 - 09:33:52	0	77	61	20JL17A	user1

Backward Enter Value to update Tag3 (Press.): Forward

Main Username: user1
Group: Default

Trend Buffer

Limitations

Depending on HMI Model: Trend Memory ranges from 50 MB to 500 MB

Sample Image: for 20 Tag, 5 min Sampling and Buffer size 50 MB

Number Of tags	20		
SAMPLING RATE (in sec)	86400		
size of 1 sample		191	Tags*9+11
Number Of samples	150000		
Hours	3600000		
Days	150000		
Required Buffer size		28650000	Number Of sample * size 1 sample
Available Buffer size	52428800		
Max Possibel Number of samples		274400	Avalaible buffer size/Size 1 sample
	Hours	6585600	
	Days	274400	9146.666667
	Years	751.7808219	
Available Buffer size(check panel Model)	Copy to available Buffer size		
50MB = 52428800 for ex Series	52428800		
500MB = 524288000 for PC runtime	524288000		

Trend Buffer

Limitations

Depending on HMI Model: Trend Memory ranges from 50 MB to 500 MB

Sample Image: for 20 Tag, 5 min Sampling and Buffer size 500 MB

Number Of tags	20		
SAMPLING RATE (in sec)	86400		
size of 1 sample		191	Tags*9+11
Number Of samples	150000		
Hours	3600000		
Days	150000		
Required Buffer size		28650000	Number Of sample * size 1 sample
Available Buffer size	524288000		
Max Possibel Number of samples		2744900	Avalaible buffer size/Size 1 sample
	Hours	65877600	
	Days	2744900	91496.66667
	Years	7520.273973	
Available Buffer size(check panel Model)	Copy to available Buffer size		
50MB = 52428800 for ex Series	52428800		
500MB = 524288000 for PC runtime	524288000		



Signed PDF Report



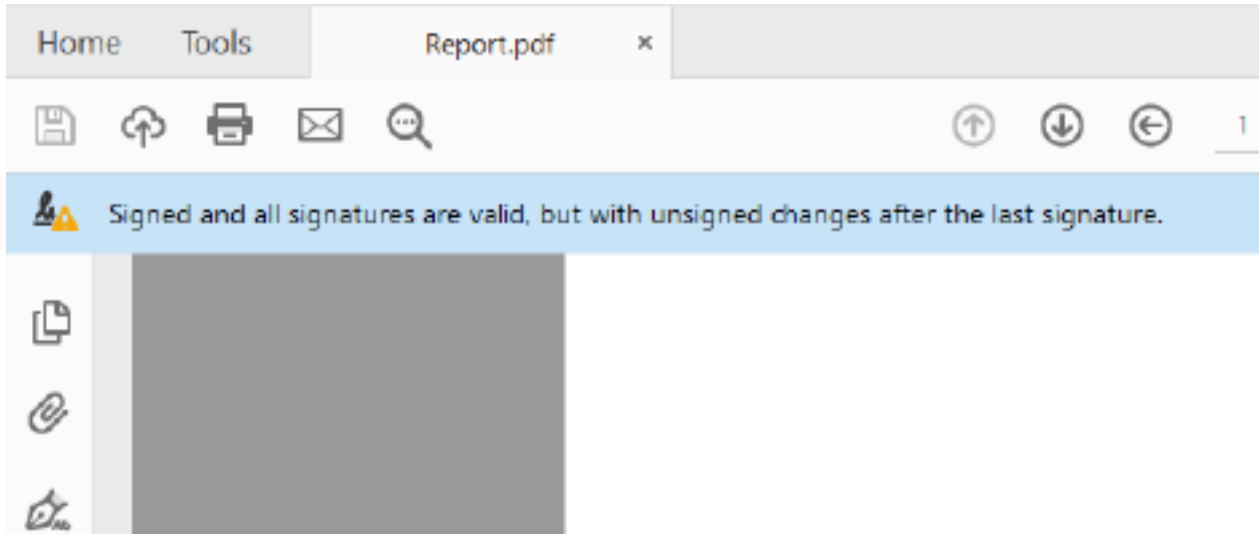
Signed PDF Report

x.509 certificate signed from a Certificate Authority

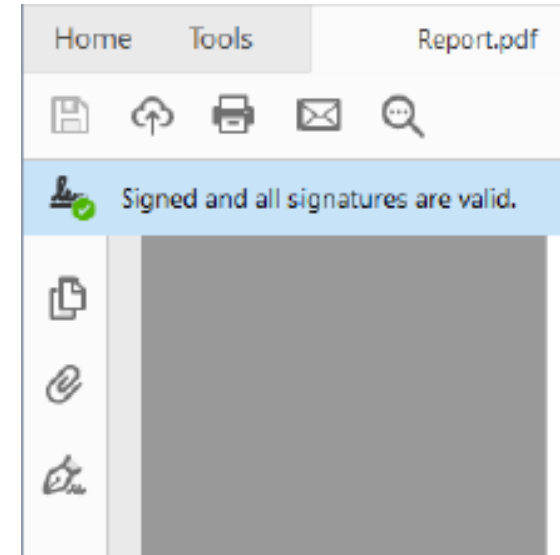
When you open the file, the PDF reader tries to decide if the signature is valid then it looks at the certificate used to sign the document.

If the document has been modified, it will be highlighted with a different message.

Modified PDF



Valid PDF



Signed PDF Report

Sample

The screenshot shows the Adobe Acrobat Pro DC interface. The title bar indicates the file is "Blender1_DataLog_727AB1_20200728_221620.pdf". The menu bar includes File, Edit, View, Window, and Help. The toolbar shows various navigation and editing tools. A blue notification bar at the top states "At least one signature has problems." and includes a "Signature Panel" button. The Signature Panel on the left shows a list of signatures, with the first one, "Rev. 1: Signed by HMI-1399", highlighted. A blue arrow points from the notification bar to this signature. The signature details are expanded, showing the following text: "Signature validity is unknown: Document has not been modified since this signature was applied. Signer's identity is unknown because it has not been included in y. Signing time is from the clock on the signer's computer." Below this, the "Signature Details" section is visible, showing "Last Checked: 2020.07.28 22:32:11 +05'30'", "Field: HMI (invisible signature)", and a link "Click to view this version". The main content area displays the report header: "Batch Name: 727AB1" and "Data Log Report". Below the header is a table with the following data:

Timestamp	TEMP	HUMI	PRESS	BatchName
28/07/2020 - 18:22:01	16	8	0	
28/07/2020 - 18:22:02	16	8	0	
28/07/2020 - 18:22:03	16	8	0	
28/07/2020 - 18:22:04	16	8	0	
28/07/2020 - 18:22:05	16	8	0	
28/07/2020 - 18:22:06	16	8	0	
28/07/2020 - 18:22:07	16	8	0	
28/07/2020 - 18:22:08	16	8	0	

Signed PDF Report

Sample Log Report:
(Max Pages = 32)

check21_Graphic Report 1_20200515_165728.pdf - Adobe Acro...
File Edit View Window Help
Home Tools check21_... x Sign In

PDF REPORT 15.05/2020 - 16:57:30

Trend Table

Timestamp	Temp	Press	Humid	Err	Mig
15/05/2020 - 16:54:50	0	0	0	No Data	No Data
15/05/2020 - 16:54:55	50	8	16	0	
15/05/2020 - 16:55:00	86	16	33	0	
15/05/2020 - 16:55:05	99	25	50	0	
15/05/2020 - 16:55:10	86	33	66	1	
15/05/2020 - 16:55:15	49	41	83	1	
15/05/2020 - 16:55:20	0	50	99	1	
15/05/2020 - 16:55:25	0	58	83	1	
15/05/2020 - 16:55:30	0	66	66	1	
15/05/2020 - 16:55:35	0	75	49	0	
15/05/2020 - 16:55:40	0	83	33	1	
15/05/2020 - 16:55:45	0	91	16	0	
15/05/2020 - 16:55:50	0	0	0	1	
15/05/2020 - 16:55:55	50	8	16	1	
15/05/2020 - 16:56:00	86	16	33	1	
15/05/2020 - 16:56:05	99	25	50	1	
15/05/2020 - 16:56:10	86	33	66	1	
15/05/2020 - 16:56:15	49	41	83	1	
15/05/2020 - 16:56:20	0	50	99	1	
15/05/2020 - 16:56:25	0	58	83	1	
15/05/2020 - 16:56:30	0	66	66	1	
15/05/2020 - 16:56:35	0	75	49	1	
15/05/2020 - 16:56:40	0	83	33	1	
15/05/2020 - 16:56:45	0	91	16	1	
15/05/2020 - 16:56:50	0	0	0	1	
15/05/2020 - 16:56:55	50	8	16	1	
15/05/2020 - 16:57:00	86	16	33	1	
15/05/2020 - 16:57:05	99	25	50	1	
15/05/2020 - 16:57:10	86	33	66	1	
15/05/2020 - 16:57:15	49	41	83	1	
15/05/2020 - 16:57:20	0	50	99	1	

Name Sign Date
Print By: Checked By:

Signed PDF Report

Sample Audit Report:
(Max Pages = 32)

check21_Graphic Report 1_20200515_165728.pdf - Adobe Acro...
File Edit View Window Help
Home Tools check21_... x ? ? ? Sign In

15/05/2020 - 16:57:29
PDF REPORT

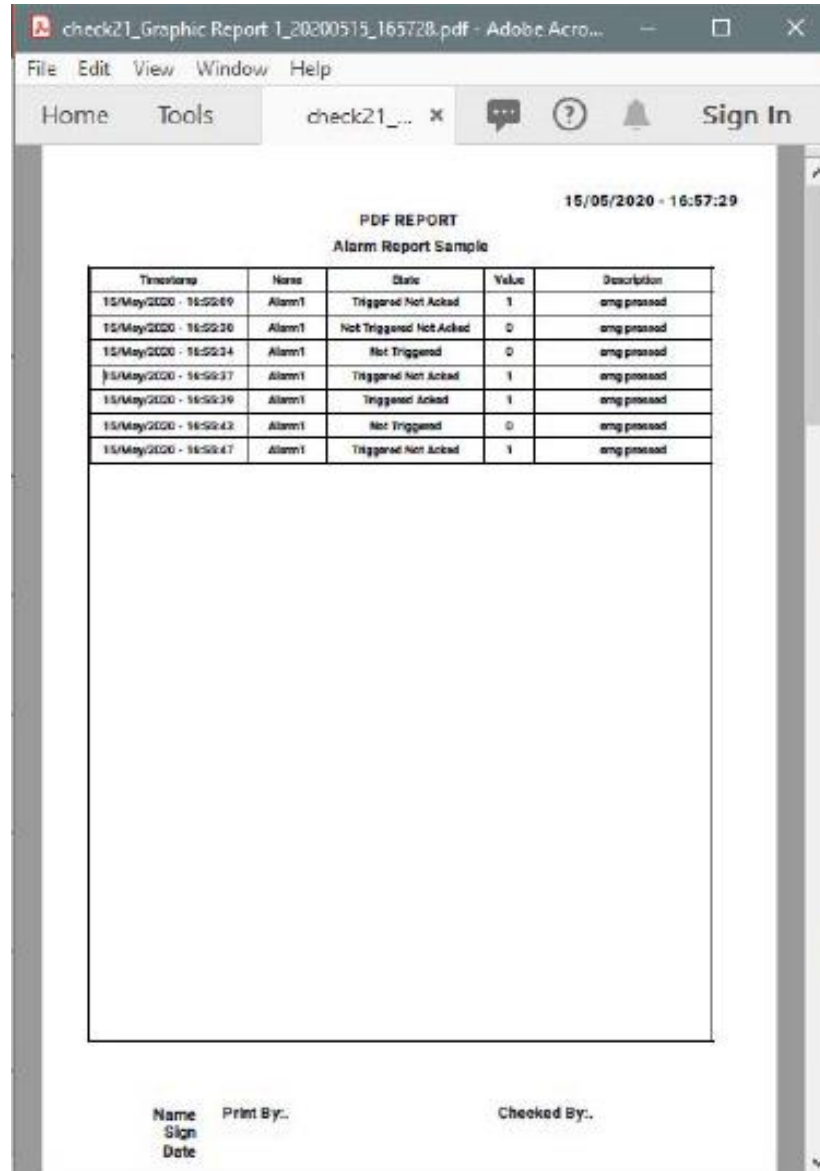
Audit Report Sample

Record ID	Timestamp	Username	Operation	Information
1	15/05/2020 - 16:56:00	SYSTEM_IDAL	SYSTEM_POWERON	ERROR ON
2	15/05/2020 - 16:56:51	admin	LOGIN	1
3	15/05/2020 - 16:52:00	admin	WRITE_TAG	Tag 1;2;1;comment 1
4	15/05/2020 - 16:55:36	admin	WRITE_TAG	Tag 1;1;comment 2
5	15/05/2020 - 16:55:34	admin	ACK_ALARM	Alarm 1;comment 2
6	15/05/2020 - 16:55:37	admin	WRITE_TAG	Tag 1;3;1;comment 2
7	15/05/2020 - 16:55:29	admin	ACK_ALARM	Alarm 1;comment 2
8	15/05/2020 - 16:55:43	SYSTEM_IDAL	RECIPE_WRITE_TAG	Tag 1;1;comment 2
9	15/05/2020 - 16:55:43	admin	DOWNLOAD_RECIPE	Recipe 0;Set 0;comment 2
10	15/05/2020 - 16:55:47	admin	WRITE_TAG	Tag 1;3;1;comment 2
11	15/05/2020 - 16:55:49	admin	UPLOAD_RECIPE	Recipe 0;Set 0;comment 2
12	15/05/2020 - 16:55:54	admin	UPLOAD_RECIPE	Recipe 0;Set 1;comment 2
13	15/05/2020 - 16:55:54	admin	UPLOAD_RECIPE	Recipe 0;Set 1;comment 2
14	15/05/2020 - 16:56:16	admin	ADD_USER	1;user 1
15	15/05/2020 - 16:56:28	admin	EDIT_USER	1;user 1;inactive
16	15/05/2020 - 16:56:28	admin	DELETE_USER	1;user 1
17	15/05/2020 - 16:56:46	admin	CHANGE_PASSWORD	1
18	15/05/2020 - 16:56:52	admin	LOGOUT	1
19	15/05/2020 - 16:56:52	user 1	LOGIN	Login failed
20	15/05/2020 - 16:57:00	admin	LOGIN	1
21	15/05/2020 - 16:57:11	admin	LOGOUT	1
22	15/05/2020 - 16:57:18	admin	LOGIN	1
23	15/05/2020 - 16:57:28	admin	PRINT_GRAPHICS_REPORT	Graphic Report 1

Name Sign Date Print By: Checked By:

Signed PDF Report

Sample Alarm Report:
(Max Pages = 64)



The screenshot shows a PDF report viewer window titled "check21_Graphic Report 1_20200515_165728.pdf - Adobe Acro...". The window has a menu bar with "File", "Edit", "View", "Window", and "Help". Below the menu bar are tabs for "Home" and "Tools", and a "Sign In" button. The report content is centered and includes the following text:

PDF REPORT 15/05/2020 - 16:57:29
Alarm Report Sample

Timestamp	Name	State	Value	Description
15/May/2020 - 16:55:59	Alarm1	Triggered Not Acked	1	smg pressed
15/May/2020 - 16:55:20	Alarm1	Not Triggered Not Acked	0	smg pressed
15/May/2020 - 16:55:24	Alarm1	Not Triggered	0	smg pressed
15/May/2020 - 16:55:37	Alarm1	Triggered Not Acked	1	smg pressed
15/May/2020 - 16:55:39	Alarm1	Triggered Acked	1	smg pressed
15/May/2020 - 16:55:43	Alarm1	Not Triggered	0	smg pressed
15/May/2020 - 16:55:47	Alarm1	Triggered Not Acked	1	smg pressed

Below the table, there are three fields for user information:

Name Print By: Checked By:
Sign
Date

Signed PDF Report

Save Location / Storage

Can be stored at multiple locations:

- USB
- SD Card
- HMI Internal
- PC location

Image of Sample Project

The screenshot displays the 'Signed PDF Report' interface. At the top right, the 'Batch Name' is 'JL27B12'. The main area is divided into several sections:

- Select location to save PDF:** A dropdown menu is open, showing options: USB (selected), SD, RUNTIME, INTERNAL, and Enter Path. Below this, two text boxes show the save paths: '/mnt/usbmemory/report' and '/mnt/usbmemory/reportbackup'.
- Report to Print:** A vertical stack of five green buttons: 'Date Log Report', 'Alarm Report', 'Audit Report', and 'All in One REPORT'.
- Status and Control:** A table-like section showing 'Printing Status' (idle), 'Printing %' (100), 'Printing Queue' (0), and 'Printing Error'. Below this, 'USB Status' (1) and 'SD Status' (1) are shown with 'Safely Remove USB' and 'Safely Remove SD' buttons respectively. 'USB FreeSpace' is 30655692800 and 'SD FreeSpace' is 1012289536.
- Footer:** A navigation bar with 'Main' and a home icon, 'Username user1', 'Group Default', 'Machine Name: Blender1', and the file path 'Blender1_DataLog_JL27B12_20200727_120905.pdf'.

Signed PDF Report

Transfer to PC

Manually:

- Taking out USB (Pen Drive) and SD card
- Using Instech Client software in PC
- Using FTP Client in PC

Automatically:

- Using HMI as FTP CLIENT we can transfer SIGNED PDF to PC.
- Need too define PC as FTP Server, So whenever FTP Server is available HMI can automatically transfer file to PC.

Image of Sample Project

The screenshot shows an HMI interface titled "Report BackUp to PC" with a "Batch Name:" field and a USB icon. The interface is divided into several sections:

- Using JMClient:** Instructions to connect to the panel using JMobile Client with (admin/admin) username/password. A "Copy from HMI" button is present.
- Using FTP Client:** Instructions to open a new browser and enter "ftp://HMI IP ADDRESS" ENTER. A sample "FTP://192.168.225.29" is provided.
- Using FTP Server on PC:** A configuration table for the FTP server.
- FTP Configuration Table:**

FTP Server IP :	192.168.225.54
FTP Server user:	admin
FTP Server Password :	admin
FileName	ExDR_210FR_V10_audit_report_20200727_102622.pdf
FTP Status:	2
FTP Current CMD :	Put
FTP Progress :	100
FTP Error Msg.	

Below the configuration table, there is a green "ENABLE FTP TRANSFER" button. At the bottom of the interface, there is a navigation bar with a "Main" button and a home icon, and a user information section showing "Username user1" and "Group Default".

Thank you!