The details of VR18 in compliance with FDA 21 CFR part 11

FDA 21 CFR part 11 compliance

On August 20th 1997 the Food and Drug Administration made 21 CFR Part 11 came into effective. This regulation is summarized as follows:

"The Food and Drug Administration (FDA) is issuing regulations that provide criteria for acceptance by FDA, under certain circumstances, of electronic records, electronic signatures, and handwritten signatures executed to electronic records as equivalent to paper records and handwritten signatures executed on paper. These regulations, which apply to all FDA program areas, are intended to permit the widest possible use of electronic technology, compatible with FDA's responsibility to promote and protect public health. The use of electronic records as well as their submission to FDA is voluntary."

Summary

The Paperless Recorders have been designed to meet the standards set out in CFR 21 part 11 and it can be used as part of a validated system.

1) All process data recorded by Paperless Recorders is protected by an Encrypted "Digital Signature" to ensure the authenticity of these records.

2) Solid state flash memory is used to provide secure storage of data that is not reliant on battery back-up and which is not subject to magnetic fields.

3) Historical Viewer review software provides the ability to view the data records and audit trails in a human readable form.

4) User id and Password are provided in the recorders to limit access to authorized personnel.

5) A detailed audit log accompanies all process data recorded by a VR18 Paperless Recorder. All system events including configuration changes, power failures are logged. All entries are time and date and time stamped including an operator id.

FDA 21 CFR Part 11 Subpart B, Section 11.10: Controls for modification.
'Persons who use closed systems to create, modify, maintain, or transmit electronic records shall employ procedures and controls designed to ensure the authenticity, integrity, and when appropriate the confidentiality of electronic records, and can ensure that the signer cannot repudiate the signed record as not genuine."

All process data recorded by paperless recorder are in proprietary (tamper-proof) format and read-only from normal operator interface. Via the use of Historical Viewer data review software "digital signature" can be added and checked to validate the integrity of the data. If any part of the data record is changed the Historical Viewer software will warn the user of the invalid nature of the record.
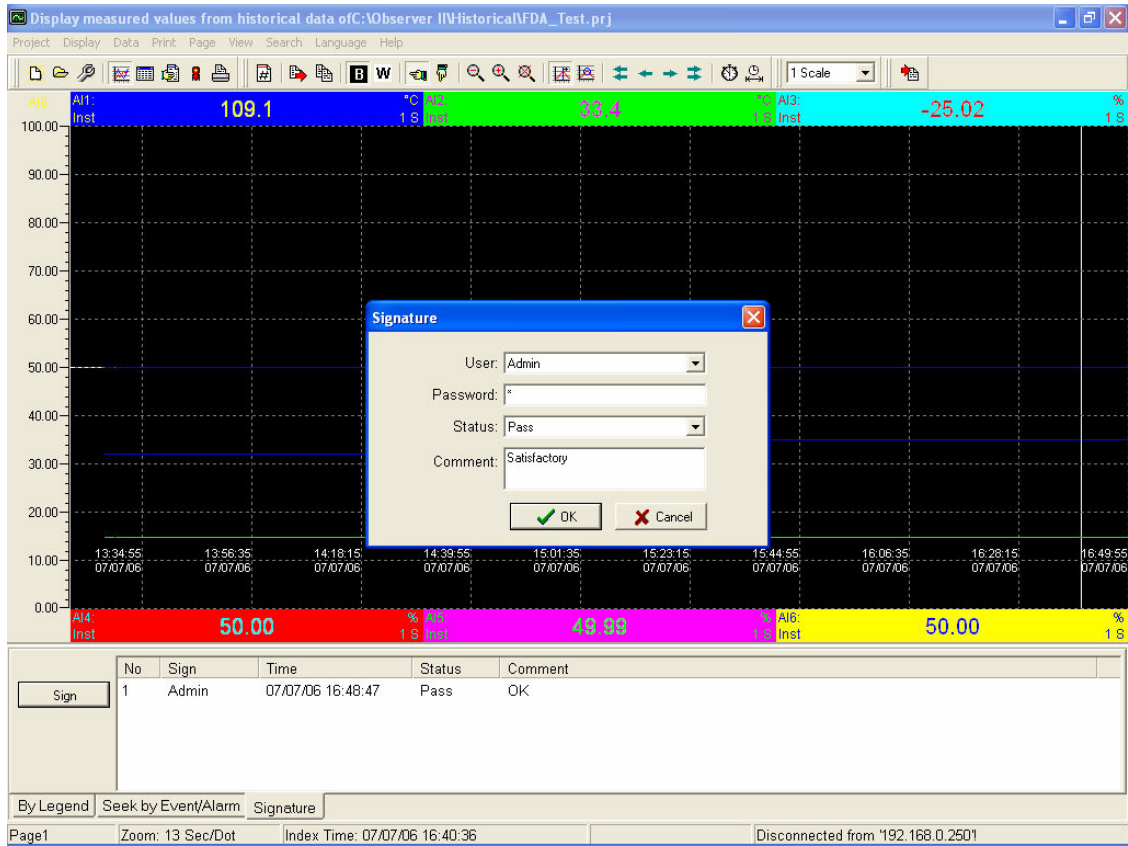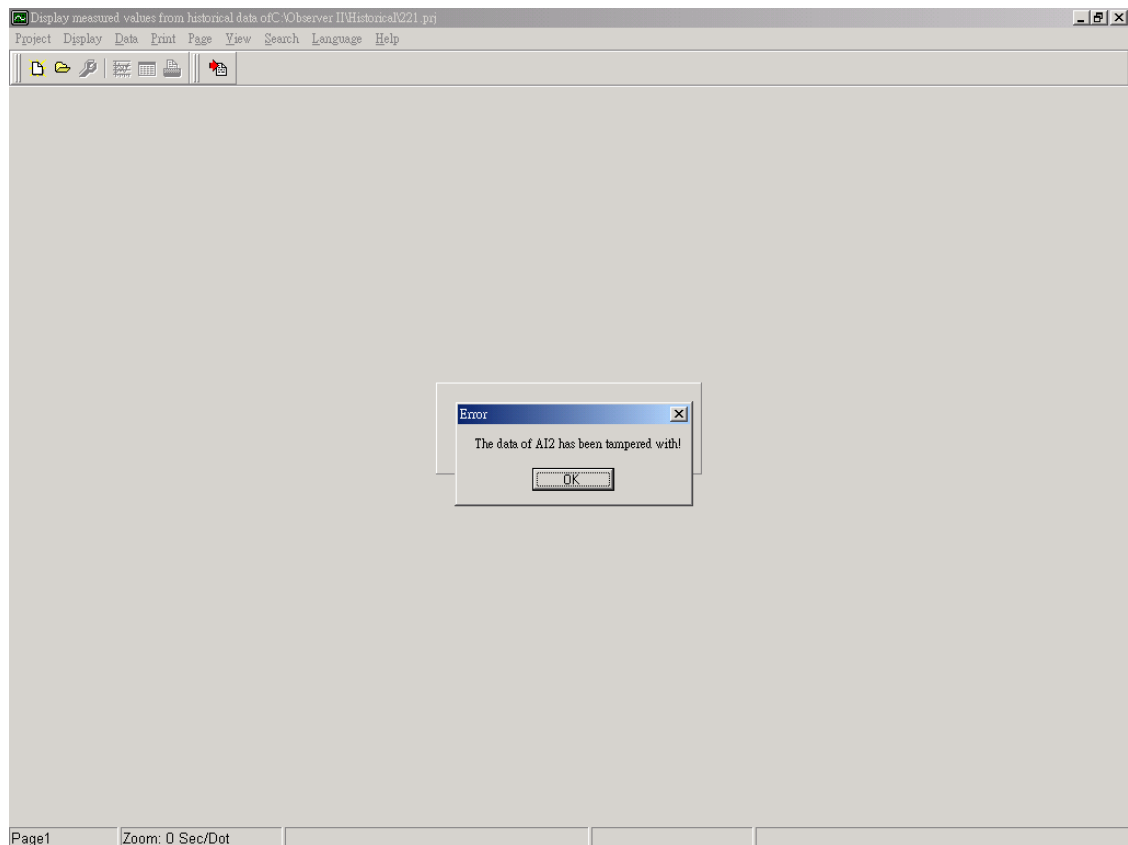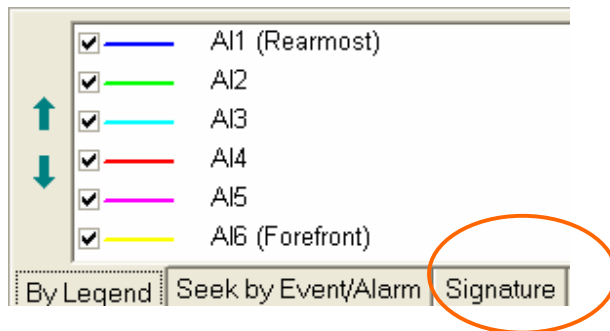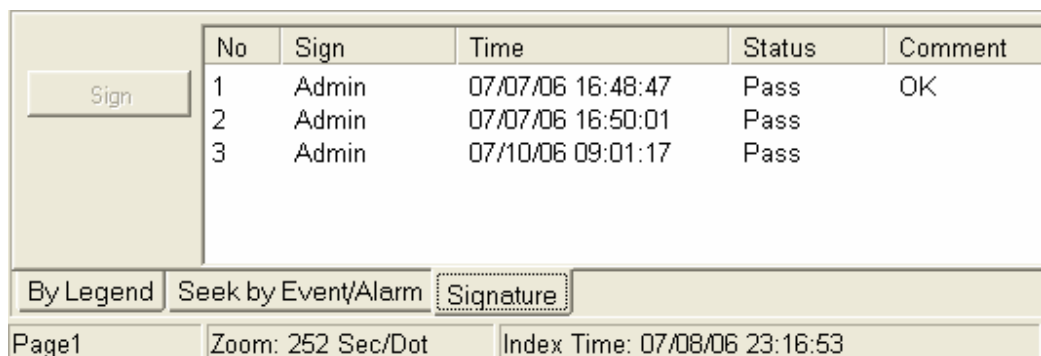
Procedure for sign of the records

1. Open historical viewer

2. Log in with specific user already created.
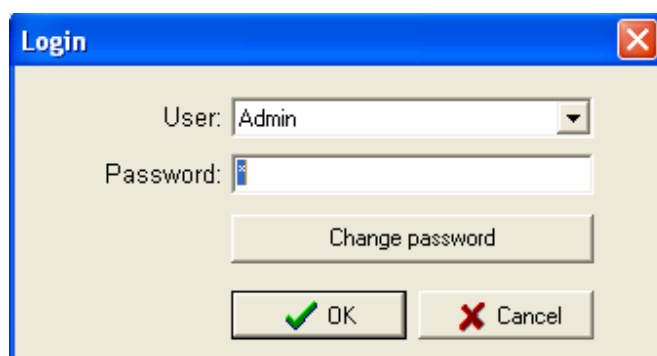
3. Click on Import measured data icon . This will import all data from recorder to PC.

4. Check all the data.

5. Then click on Signature at task bar available at bottom side of the screen in the historical viewer

6. Then signature section will appear as follows.

7. By default "Sign" button will be disabled as shown above. Once latest data is imported from recorder to PC using Icon, then "Sign" button is enabled. Now user can sign the record with his comments as per the following image.
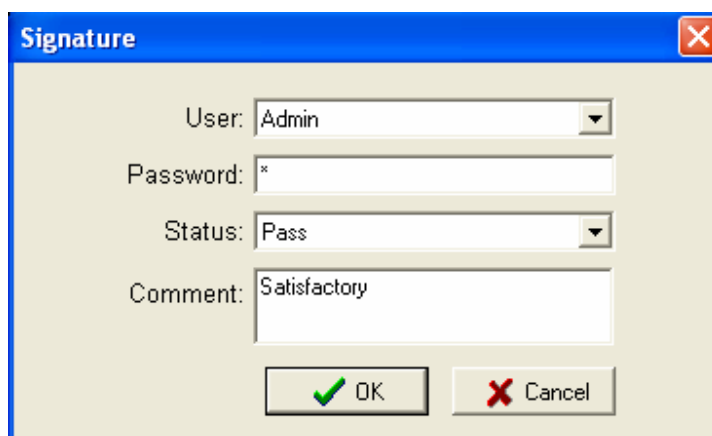
8. Status: Select Pass/ Fail
    Comment: Give your comments about the checked data
    Then press "OK" to complete signature process which is equal to signing of
   paper record.

FDA CFR21 Part 11 Section 11.10 (b)

"The ability to generate accurate and complete copies of records in both human readable and electronic form suitable for inspection, review, and copying by the agency (FDA"

Paperless recorder can create process data files on Compact Flash memory cards in proprietary format. These data files are created from secure records stored in internal flash memory. Error detection algorithms are employed to ensure that the stored data faithfully represents the actual raw measurements made by the recorder. Each write to the archive media is also verified to ensure the integrity of the data record. The archived process data files can be viewed using the Historical Viewer review software. The data can be viewed and printed in graphical formats. Standard spreadsheet formats (e.g. Microsoft Excel) of the archived data files can be created for viewing by users who do not have the review software.
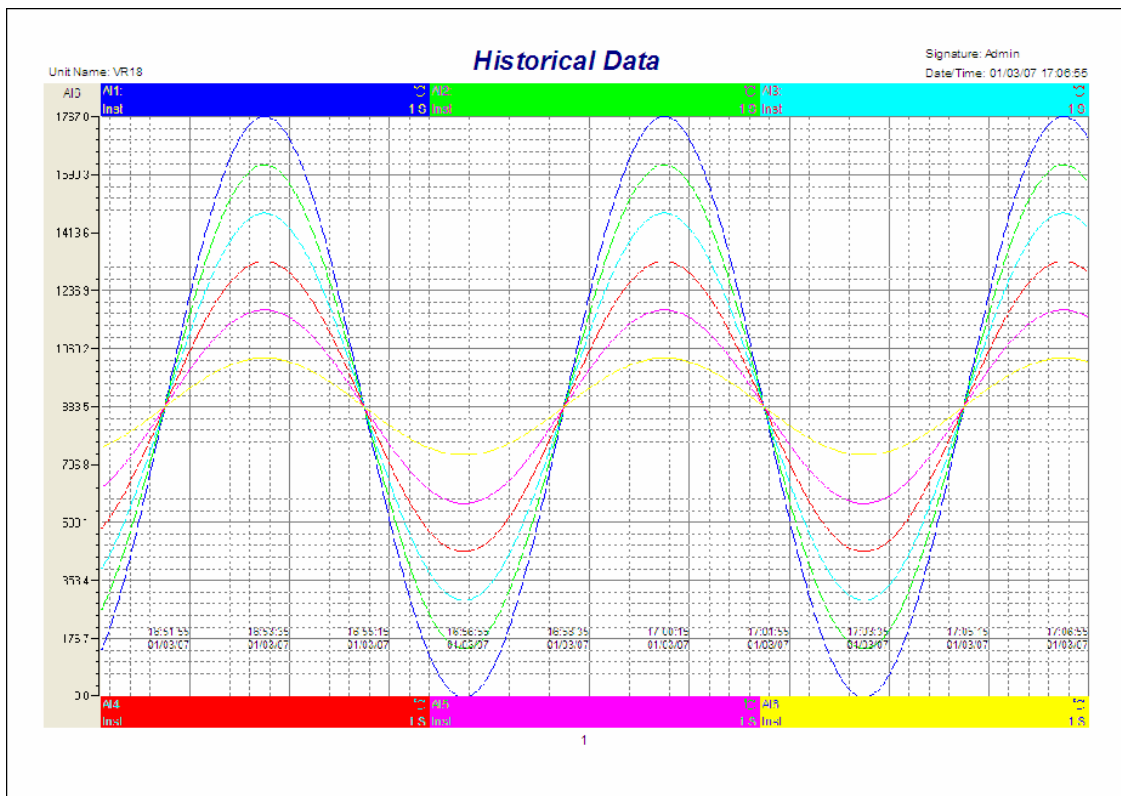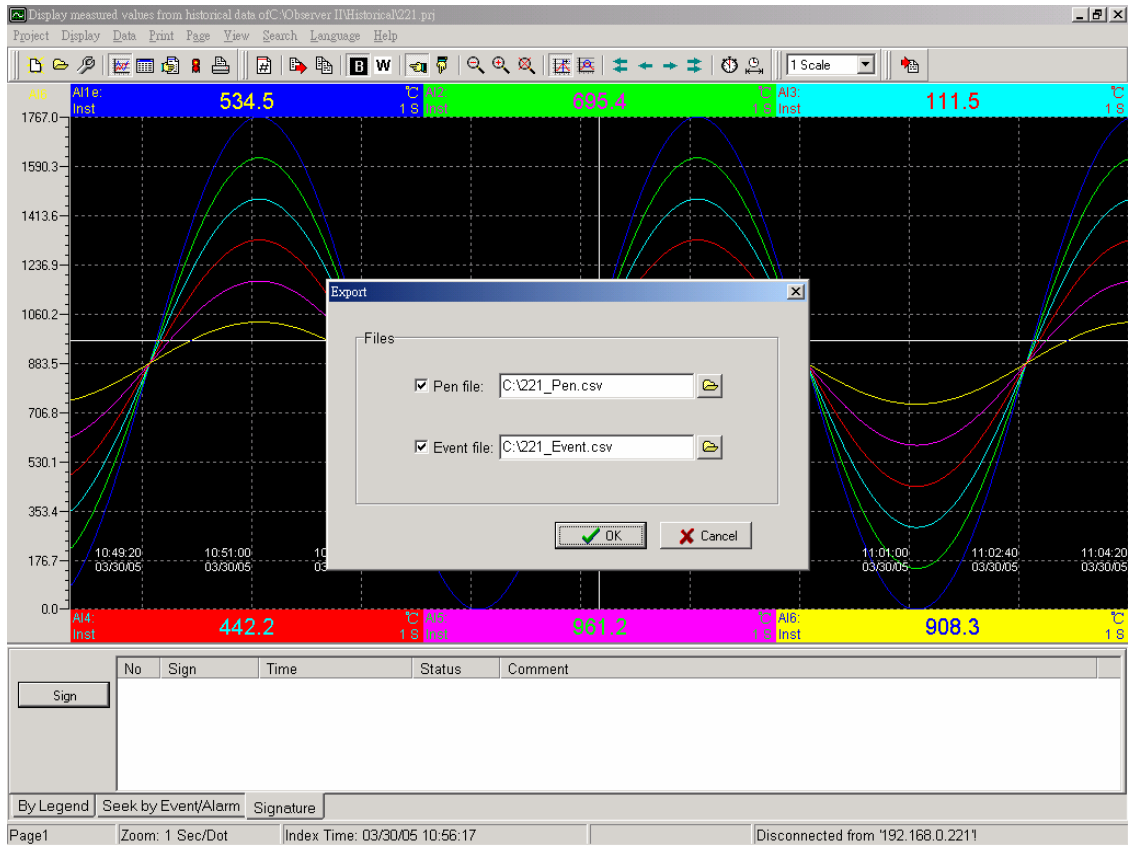
	A	B	C	D	E	F	G	H	I	J	K	L	M
1	Date/Time	AI1	AI10	AI11	AI12	AI13	AI14	AI15	AI16	AI17	AI18	AI2	AI3
2		Instant	Instant	Instant	Instant	Instant	Instant	Instant	Instant	Instant	Instant	Instant	Instant
3		℃	℉	℉	℉	%	%	%	%	%	%	℃	℃
4	2005/3/28 13:24	433	1198.4	2211.6	1886	99.2	82.8	66.4	33.6	17.2	0.8	576.9	72.3
5	2005/3/28 13:24	415.4	1189.4	2200.7	1880.7	97.2	81.46	65.73	34.26	18.53	2.8	556.3	65.5
6	2005/3/28 13:24	397.9	1180.4	2189.7	1875.4	95.2	80.13	65.06	34.93	19.86	4.8	535.8	58.7
7	2005/3/28 13:24	380.4	1171.4	2178.8	1870.1	93.2	78.8	64.4	35.6	21.2	6.8	515.3	51.9
8	2005/3/28 13:24	362.9	1162.4	2167.9	1864.8	91.2	77.46	63.73	36.26	22.53	8.8	494.9	45.2
9	2005/3/28 13:24	345.5	1153.4	2157	1859.5	89.2	76.13	63.06	36.93	23.86	10.8	474.6	38.4
10	2005/3/28 13:24	328.2	1144.4	2146.1	1854.2	87.2	74.8	62.4	37.6	25.2	12.8	454.4	31.7
11	2005/3/28 13:24	311	1135.4	2135.1	1848.9	85.2	73.46	61.73	38.26	26.53	14.8	434.4	25.1
12	2005/3/28 13:24	294	1126.4	2124.2	1843.6	83.2	72.13	61.06	38.93	27.86	16.8	414.4	18.5
13	2005/3/28 13:24	277.1	1117.4	2113.3	1838.3	81.2	70.8	60.4	39.6	29.2	18.8	394.7	11.9
14	2005/3/28 13:24	260.3	1108.4	2102.4	1833	79.2	69.46	59.73	40.26	30.53	20.8	375.1	5.5
15	2005/3/28 13:24	243.8	1099.4	2091.5	1827.7	77.2	68.13	59.06	40.93	31.86	22.8	355.8	-.:
16	2005/3/28 13:25	227.4	1090.4	2080.5	1822.4	75.2	66.8	58.4	41.6	33.2	24.8	336.6	-7.:
17	2005/3/28 13:25	211.2	1081.4	2069.6	1817.1	73.2	65.46	57.73	42.26	34.53	26.8	317.7	-13.6
18	2005/3/28 13:25	195.3	1072.4	2058.7	1811.7	71.2	64.13	57.06	42.93	35.86	28.8	299.1	-19.7
19	2005/3/28 13:25	179.6	1063.4	2047.8	1806.4	69.2	62.8	56.4	43.6	37.2	30.8	280.8	-25.8
20	2005/3/28 13:25	164.1	1054.4	2036.9	1801.1	67.2	61.46	55.73	44.26	38.53	32.8	262.7	-31.8
21	2005/3/28 13:25	148.9	1045.4	2025.9	1795.8	65.2	60.13	55.06	44.93	39.86	34.8	245	-37.6
22	2005/3/28 13:25	134.1	1036.4	2015	1790.5	63.2	58.8	54.4	45.6	41.2	36.8	227.6	-43.4
23	2005/3/28 13:25	119.5	1027.4	2004.1	1785.2	61.2	57.46	53.73	46.26	42.53	38.8	210.6	-49
24	2005/3/28 13:25	105.2	1018.4	1993.2	1779.9	59.2	56.13	53.06	46.93	43.86	40.8	193.9	-54.6
25	2005/3/28 13:25	91.3	1009.4	1982.3	1774.6	57.2	54.8	52.4	47.6	45.2	42.8	177.6	-60
26	2005/3/28 13:25	77.7	1000.4	1971.3	1769.3	55.2	53.46	51.73	48.26	46.53	44.8	161.8	-65.2
27	2005/3/28 13:25	64.4	991.4	1960.4	1764	53.2	52.13	51.06	48.93	47.86	46.8	146.3	-70.3
28	2005/3/28 13:25	51.6	982.4	1949.5	1758.7	51.2	50.8	50.4	49.6	49.2	48.8	131.3	-75.3
29	2005/3/28 13:25	39.1	973.4	1938.6	1753.4	49.2	49.46	49.73	50.26	50.53	50.8	116.7	-80.1
30	2005/3/28 13:25	27	964.4	1927.7	1748.1	47.2	48.13	49.06	50.93	51.86	52.8	102.6	-84.8

FDA CFR21 Part 11 Section11.10 (c)
"Protection of records to enable their accurate and ready retrieval throughout the records retention period"

Paperless recorder use solid state flash memory, for data storage, in the form of Compact Flash card. Data retention for this device is specified at a minimum of 10 years. It provides Zero power data retention i.e. the data integrity is not dependent on battery back-up. The data is not affected by magnetic fields. For even longer term data storage the archive files can be copied to CDROM or to a network file server.

FDA CFR21 Part 11 Section11.10 (d)
"Limiting system access to authorized individuals."

Paperless recorder provide the ability to limit access to the instruments configuration and critical operator functions. For each user a unique id and password can be created for access to the configuration parameters. The id and password can be alphanumeric and up to 8 characters in length. In order to gain access to the configuration parameters, a valid operator id and password combination should to be entered. Any modification of the instruments configuration is recorded in the audit log identifying the user responsible for the change. Paperless recorder will logout automatically after a period of inactivity say 10 minutes.

| 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 | 29 | 30 | ◀ ▶ |

User: | Henry

Password: Please enter a new password when first time

Security Level: | Operator ▾ |

Time of validity: | 30 Days valid account ▾ |

Days of expiration: Unlimited time

↑

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←

→

↵ Enter

Back

<   >

User 30

| 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 | 29 | 30 |

User: Henry

Password: Please enter a new password when first time login.

Security Level: Operator

Time of validity: 30 Days valid Password

Days of expiration: Unlimited time

evnt 0% mem 96% CF 93% 17:49:54 07/03/06

AI1 °C | Ins | AI2 °C | Ins | AI3 °C | Ins
1s | 1s | 1s

1000.0
1370.0
400.0
900.0
1820.0
1767.0

Login ☒

User: Admin ▼

Password:

Change password

7:44:22
7/03/06 | 17:46:02
07/03/06 | 17:47:42
07/03/06 | 17:49:22
07/03/06

-120.0
-200.0
-250.0
-100.0
0.0
0.0

AI4 °C | Ins | AI5 °C | Ins | AI6 °C | Ins
1s | 1s | 1s

↑

↓

↵
Enter

OK

FDA CFR21 Part 11 Section11.10 (e)
"Use of secure, computer-generated, time-stamped audit trails to independently record the date and time of operator actions that create, modify or delete electronic records", Record changes shall not obscure previously recorded information. Such audit trail documentation shall be retained at least as long as that required for the subject electronic records and shall be available for agency review and copying"

The Paperless recorders automatically produce a time stamped audit trail that includes power failure and recovery, configuration changes, data dumping and clearing, critical operator functions. This information is stored in an audit log which can be archived to a permanent file on Compact flash. A separate alarm/event log automatically produces a time stamped record of all alarm state changes and can also be archived to a permanent file.

Mode
Event

Event/Alarm	Report

Ack	Type	Source	Active Time	Clear Time	Value
191	System	PowOff	01/27 03:14:05		
192	System	PowOn	01/27 03:14:05		
193☐	LoAlarm	AI7	01/27 03:14:20		-175.9
194☐	LoLoAlarm	AI7	01/27 03:14:20		-175.9
195☐	LoAlarm	AI8	01/27 03:14:20		-83.1
196☐	LoLoAlarm	AI8	01/27 03:14:20		-83.1
197☐	LoAlarm	AI9	01/27 03:14:20		-219.9
198☐	LoAlarm	AI13	01/27 03:14:20		0.80
199☐	LoLoAlarm	AI13	01/27 03:14:20		0.80
200☐	LoAlarm	AI14	01/27 03:14:20		17.20
201☐	HiAlarm	AI17	01/27 03:14:20		82.80
202☐	HiAlarm	AI18	01/27 03:14:20		99.20
203☐	HiHiAlarm	AI18	01/27 03:14:20		99.20
204☐	HiAlarm	AI1	01/27 03:15:29		781.8
205☐	HiAlarm	AI2	01/27 03:15:50		1060.5
206☐	HiHiAlarm	AI1	01/27 03:15:57		864.7
207	Login	Admin	01/27 03:15:03		
208	Logout	Admin	01/27 03:15:07		
209	Login	Admin	01/27 03:15:09		
210☐	HiHiAlarm	AI2	01/27 03:15:39		1176.0
211☐	HiAlarm	AI3	01/27 03:15:39		270.8
212☐	HiAlarm	AI13	01/27 03:15:54		80.80

Ack

Back

Dump	Clear	Operate	Config	Logout	Shutdown

Project   Display   Data   Print   Page   View   Search   Language   Help

Ack	Type	Source	Active Time	Clear Time	Value
1	NetDump	Admin	03/29/05 15:41:18		
2 ☐	HiAlarm	AI1e	03/29/05 15:41:19	Terminated	945.9
3 ☐	HiHiAlarm	AI1e	03/29/05 15:41:19	Terminated	945.9
4 ☐	HiAlarm	AI2	03/29/05 15:41:19	Terminated	1176.0
5 ☐	HiHiAlarm	AI2	03/29/05 15:41:19	Terminated	1176.0
6 ☐	HiAlarm	AI3	03/29/05 15:41:19	Terminated	270.7
7 ☐	HiAlarm	AI13	03/29/05 15:41:28	Terminated	80.80
8 ☐	LoAlarm	AI18	03/29/05 15:41:28	Terminated	19.20
9 ☐	HiHiAlarm	AI13	03/29/05 15:41:35	Terminated	87.80
10 ☐	LoLoAlarm	AI18	03/29/05 15:41:35	Terminated	12.20
11 ☐	HiAlarm	AI14	03/29/05 15:41:43	Terminated	80.53
12 ☐	LoAlarm	AI17	03/29/05 15:41:43	Terminated	19.47
13 ☐	HiAlarm	AI7	03/29/05 15:42:48	Terminated	1436.9
14 ☐	HiAlarm	AI8	03/29/05 15:43:00	Terminated	1942.2
15 ☐	HiHiAlarm	AI7	03/29/05 15:43:03	Terminated	1588.1
16 ☐	HiHiAlarm	AI8	03/29/05 15:43:18	Terminated	2154.2
17 ☐	HiAlarm	AI9	03/29/05 15:43:18	Terminated	521.1
18 ☐	LoAlarm	AI1e	03/29/05 15:44:09	Terminated	98.3
19 ☐	LoAlarm	AI2	03/29/05 15:44:19	Terminated	109.7
20 ☐	LoLoAlarm	AI1e	03/29/05 15:44:22	Terminated	15.4
21 ☐	LoLoAlarm	AI2	03/29/05 15:44:39	Terminated	-6.0
22 ☐	LoAlarm	AI3	03/29/05 15:44:39	Terminated	-120.7
23 ☐	LoAlarm	AI13	03/29/05 15:44:48	Terminated	19.20
24 ☐	HiAlarm	AI18	03/29/05 15:44:48	Terminated	80.80
25 ☐	LoLoAlarm	AI13	03/29/05 15:44:55	Terminated	12.20
26 ☐	HiHiAlarm	AI18	03/29/05 15:44:55	Terminated	87.80
27 ☐	LoAlarm	AI14	03/29/05 15:45:03	Terminated	19.47
28 ☐	HiAlarm	AI17	03/29/05 15:45:03	Terminated	80.53
29 ☐	LoAlarm	AI7	03/29/05 15:46:08	Terminated	211.1
30 ☐	LoAlarm	AI8	03/29/05 15:46:20	Terminated	227.8
31 ☐	LoLoAlarm	AI7	03/29/05 15:46:23	Terminated	59.9
32 ☐	LoLoAlarm	AI8	03/29/05 15:46:38	Terminated	15.8
33 ☐	LoAlarm	AI9	03/29/05 15:46:38	Terminated	-187.1
34	NetLogout	Admin	03/29/05 15:49:26		
35	NetLogin	Admin	03/29/05 15:49:33		
36	NetLogout	Admin	03/29/05 15:49:49		
37	NetLogin	Admin	03/29/05 15:50:24		
38	NetLogout	Admin	03/29/05 15:50:44		
39	NetLogin	Admin	03/29/05 15:54:34		

FDA CFR21 Part 11 Section 11.10 (g)
"Use of authority checks to ensure that only authorized individuals can use the system, electronically sign a record, access the operation or computer system input or output device, alter a record, or perform the operation at hand."

The recorders security system outlined in part d) limits access to the system to modify any configuration parameters.

FDA CFR21 Part 11 Section 11.10 (h)
"Use of device (e.g., terminal) checks to determine, as appropriate, the validity of the source of data input or operational instruction.

System errors and input channel status are logged

FDA CFR21 Part 11 Section 11.10 (i)
"Determination that the persons who develop, maintain, or use electronic record/electronic signature systems have the education, training and experience to perform their assigned tasks."

Only suitably qualified people are employed in product design & development and their training is updated to meet advances in technology.

FDA CFR21 Part 11 Section 11.10 (k)
"Use of appropriate controls over systems documentation including:
(1) Adequate controls over the distribution of, access to, and use of documentation for system operation and maintenance.

(2) Revision and change control procedures to maintain an audit trail that documents time-sequenced development and modification of systems documentation."

A design control system is used which is fully documented and traceable. Documentation is provided for installation, configuration and operation in the instruments User Guide.

§ 11.300 Controls for identification codes/passwords.
Persons who use electronic signatures based upon use of identification codes in combination with passwords shall employ controls to ensure their security and integrity. Such controls shall include:
(a) Maintaining the uniqueness of each combined identification code and password, such that no two individuals have the same combination of identification code and password.

Any duplication of user name from a new created account will be forbidden.

(b) Ensuring that identification code and password issuances are periodically checked, recalled, or revised, (e.g., to cover such events as password aging).

The following things will automatically be done:
1. Closing the user account when the time of account limitation expires.
2. Force the user to enter a new password when the time of password expires.

Display/Change configuration data from:C:\Observer II\Historical\FDA_Test.prj

User 2

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |

User: User2

Password: Please enter a new password when first time login.

Security Level: Operator

Time of validity: Account Closed

Unlimited time
Account Closed
30 Days valid account
60 Days valid account
90 Days valid account
30 Days valid Password
60 Days valid Password
90 Days valid Password

Days of expiration:

(d) Use of transaction safeguards to prevent unauthorized use of passwords and/or identification codes, and detect and report in an immediate and urgent manner any attempts at their unauthorized use to the system security unit, and, as appropriate, to organizational management.

Any event of failed login will be logged for audit trail.