

# INSTALLATION/ OPERATIONAL QUALIFICATION For MiniTrend V5 Recorder

# **Performed By:**

Honeywell

Document created by Honeywell Inc., Ft. Washington PA - Release 1-02

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# **1.0 Introduction**

# 1.1 Objective

The objective of this Installation/Operational Qualification (IQ/OQ) Protocol is to provide documented verification that all aspects of the equipment installation adhere to the manufacturer's recommendations, appropriate safety codes, and approved company specifications and design intentions. This document also demonstrates that the user has standard operating procedures (SOPs) for operator training, written methods for the verification of the calibration of the system elements, and upkeep of the system.

In order to ensure proper installation of the Honeywell MiniTrend V5 recorder components, this protocol will establish the test procedures, specific responsibilities, and acceptance to provide evidence that:

- Hardware has been installed according to manufacturer specifications.
- Hardware has been configured in accordance with user requirements.
- Software has been installed according to the manufacturer specifications.
- Software has been configured in accordance with user requirements.
- MiniTrend V5 recorder operates in accordance with manufacturer and user specifications.

# 1.2 Scope

The scope of this document is limited to the system hardware and software components of the Honeywell MiniTrend V5 recorder. The system will include one TrendView V5 MiniTrend recorder connections to supporting utilities and a suitable PC based software application from the TrendManager V5 Suite system management software.

Excluded from this scope:

- Software:
- TrendServer Pro Software
- Web Based Usage
- File Transfer Protocol
- Fuzzy Logging
- Standard Security
- Hardware
- Standard Input Card
- No Floppy Drive Installed

## 1.3 Responsibilities

The Validation Team members are identified on users specific Validation Plan or identified on attached signature sheet for this protocol.

The Validation Team members are responsible for

- Review and approval of this protocol.
- Overseeing execution of this protocol.
- Assignment of tasks to perform defined in this protocol.
- Interfacing with all appropriate departments, as well as vendors and contract laboratories, to obtain applicable procedures, manuals, drawings, and documentation necessary for the generation of this protocol and related reports.
- Assist in resolving any deviations or regulatory compliance issues.

## 1.4 Prerequisites

According to GAMP 3, the following documentation is identified as the basic framework for specification, design and testing.

**Validation Plan -** A summary document produced by the user to define the activities, procedures, and responsibilities for establishing the performance adequacy of the system.

**User Requirement** - Produced by the user to define clearly and precisely what the user wants the system to do, and to state any constraints, regulatory, and documentation requirements.

**Functional Specification** - Usually produced by supplier and describes the detailed functions of the equipment or system, i.e. what the system will do. This protocol utilized Honeywell's MiniTrend, Mulitrend Plus V5 User Manual for its Functional Specification.

**Design / Configuration Specification -** A complete definition of the equipment or system in sufficient detail to enable it to be built.

**Standard Operating Procedures** - Standard Operating procedures specific to this system have been created. (Including compliance to 21CFR11)

## 1.5 Referenced Documents

\_\_\_\_\_

The following is a list of documents referenced by this document: (Included but not limited to: Validation Plan, User Requirement, Functional Specification, Design/Configuration Specification and applicable SOP's).

*Note:* Complete below with all applicable documentation for this system, place N/A initial and date for any spaces not required.

Document #

Location

# 2.0 System Overview

Application Software: TrendViewer, TrendManager Pro and Screen Designer

TrendViewer is a Windows <sup>TM</sup> based software package, which is shipped with all recorders and allows user to view, graph, and print data from a disk or PCMCIA card interface.

The TrendManager Pro V5 is a standalone package that allows the user to fully configure recorders, as well as archive, graph, print and export data. An integral E-mail facility allows recorder data and configurations to be sent to other users and colleagues on the plant or worldwide.

Screen Designer enables the customer to design unique displays for transfer to the recorder screen. Screen layouts can be created using any combination of indicators such as trending Charts, Digital Panel Meters (DPM), Bargraphs, Bitmaps, Digital pictures and Plant diagrams. (Protocol Addendum included only when option purchased)

The Screen Designer software design package is compatible with Minitrend V5 recorders so layouts can be transferred on to single or multiple recorders giving continuity and standardization of process data.

#### Hardware

#### MiniTrend V5

Minitrend V5 system is an advanced paperless recording system, which can be fully programmed and re-configured locally via the integral keypad, or remotely from a PC. The configuration may be transferred from the PC to the recorder on a  $3\frac{1}{2}$  " 1.44 Mb floppy disk or PCMCIA card.

The Minitrend V5 is a 4 to 16-channel recorder with 5.5-inch diagonal quarter VGA color TFT LCD. The recorder is comprised of a microprocessor-controlled measurement, recording, and graphics display system.

The V5 Paperless Chart Recorder System is used to measure and record process data in a secure tamperproof format with full audit trail facilities. The data may be sampled directly from voltage or current sources, or be obtained from thermocouple or PT100 resistance thermometer sources. Ranges and accuracies are dependent upon the options selected for the system under consideration.

Optional features include Totalization function providing up to 24 independent user programmable totalization channels, Event Markers providing the facility for the user to

tag pre-defined or real-time labels to data "events" and logging conditions, Math Expressions, High/Low/Range of Change Alarms, and Transmitter Power Supply.

The data is stored on industry standard 3 <sup>1</sup>/<sub>2</sub> " 1.44Mbyte diskettes, together with all recorder configuration details, Totalization data, and Event data. An optional additional memory card (PCMCIA card) can be used in the PCMCIA Interface which will be a standard feature. This, plus the use of the Math option offers Dual Redundancy of data storage. This is a recommended system configuration for pharmaceutical manufacturing data recording. Data is time and date stamped in a digitally encrypted format that ensures data authenticity and integrity when stored to the disk. The Trend Manager V5 Suite software enables users to view this encrypted data in human readable form. Any attempt to alter specific data points would result in corruption of the whole file. Recorded chart data in the MiniTrend V5 recorder can be replayed, scrolling backwards and forwards through a chart without affecting on-going real-time recording.

The Honeywell MiniTrend V5 presents the data as strip charts (vertical and/or horizontal), tiled charts, plan diagrams and bitmap pictures. It has the capability of displaying 10 independent user definable display screens.

Recorders may be set up locally using the integral keypad and intuitive pull down menu system, or the configuration can be set up remotely using the TrendManager V5 Suite system management software (optional). Once set up, each recorders configuration can be password protected with a full multi level password protection system. All configuration changes within the recorder are also recorded under a full audit trail monitoring system.

# **3.0 Protocol Execution**

## 3.1 Validation Methodology

This system Installation Qualification establishes which components of Honeywell MiniTrend V5 Recorder System hardware and software need to be documented, what the documents should contain, how critical information should be verified, who is responsible for generating the documentation, and the approvals required for each document.

The system Operational Qualification establishes functionality of the recorder system hardware and software and identifies which functions require testing, what documents should contain, how critical information should be verified and who is responsible for generating the documentation.

# 3.2 Protocol Documentation

DEPARTMENT (S) AND LOCATION (S) COMPANY NAME	1
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The protocol will detail various tests, which will require data collection and test summarization to be documented on the appropriate data sheets that are part of this protocol.

- All entries must be recorded legibly in permanent ink.
- All data sheets must be signed and dated by the person recording the data.
- All attachments will be inserted into protocol directly behind corresponding data sheet.
- Any findings and comments will be summarized in the appropriate comments section of each data sheet.
- Corrections to entries may be crossed off with a single line, signed and dated by the person performing the correction.

# 3.3 Protocol Amendment and Deviation

Any discrepancies found during validation testing will be fully described on the Protocol Amendment and Deviation Form. Each deviation and/or amendment will be assigned a consecutive number within the documentation of this protocol. Documentation of a deviation or amendment will include a description of the occurrence and an action/resolution summary. The decision to re-qualify, take corrective action, or justify

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the deviation will be made by appropriate personnel including but not limited to: Validation Manager, Operations, Engineering, and QA/QC departments.

Amendments will have pre-approved acceptance criteria, and all supporting documentation will be included with this test document.

Pass or fail determinations will be based on the matching of "Actual Results" with "Expected Results". All observations must be clearly detailed within the "Actual Result" field. "Pass" or "Fail" shall be indicated in the Pass/Fail column.

- All steps that are marked "Fail" ("Actual" that does not match "Expected") shall be recorded in the Protocol Amendment and Deviation form. Failures/Errors are defined as a function inherent to the system that is not operating, functioning, or capable of performing as indicated in the "Expected Results".
- Errors encountered that are not associated with functional deviations and do not affect test integrity (i.e. Typographical) may be corrected on the hard copy of the script. All corrections must be initialed and dated.

# 3.4 Acceptance Criteria

- All required Installation/Operational Qualification test scripts have been performed and all corresponding attachments are completed.
- All amendments and deviations have been adequately resolved and approved.
- The applicable system components (i.e., hardware and software) are identified and installed in accordance with manufacturers and user design specifications.
- All applicable documents, specifications, and diagrams are included and accurately represent as-built conditions.
- All standard operating procedures are identified and exist minimally in Draft format.
- All electrical and environmental requirements meet the manufacturer's requirements.

# 4.0 Test Procedure Overview

#### 4.1 Installation Qualification

#### 4.1.1 Drawing and Diagrams

The objective of this verification is to record the documentation, such as drawings and system diagrams.

#### 4.1.2 Standard Operating Procedures

The objective of this verification is to record the Standard Operating Procedures.

#### 4.1.3 Manuals and Miscellaneous Documentation

The objective of this verification is to record the documentation, such as manuals and all other applicable documentation such as: vendor audits, purchase order requisition, etc. for the Honeywell MiniTrend V5 Recorder hardware and software components.

#### 4.1.4 Inventory of Components

The objective of this verification is to identify the hardware and software components associated with Honeywell MiniTrend V5 Recorder.

#### 4.1.5 Configuration Verification

The objective of this verification is to confirm that the procedures for configuring exist and that the current configuration including but not limited to Pen, Analog Inputs, Custom Screen and Events are as documented in data sheet or design specification.

#### 4.1.6 Operating Environment

This section will verify the adequacy of the installation environment. The hardware components will be verified to be properly set with the required power, ambient temperature, and relative humidity.

#### 4.1.7 Training and Documentation

The objective is to verify that all required training for the Honeywell Trendview V5 Recorder System has been identified and training material is accessible.

#### 4.1.8 Service Contract/Support Agreement

The objective of this verification is to review the existence of service and support contract. Specific vendor need not be identified.

#### 4.1.9 Contingency and Disaster Plans

The objective of this verification is to ensure that contingency and disaster plans exist and describe measures to be taken in the event of a disaster. Plans will be inspected and reviewed to ensure that they are current, complete, and accessible to authorized personnel.

#### 4.1.10 Backup and Storage Procedures

The objective of this verification is to ensure that backup and storage procedures exist and are available to responsible personnel. This verification will also ensure that backup and storage records are properly identified, current, and complete.

#### 4.1.11 Uninterruptible Power Source (UPS) Verification

The objective of this verification is to document the uninterrupted power source, which is provided to the Trendview system providing a trustworthy and reliable data collection system.

#### 4.1.12 Physical Security

This section will verify that unauthorized users will not be able to gain access to the system.

#### 4.1.13 Data File Archiving, Storage, and Retrieval Verification

The objective of this procedure is to document that data can be stored to the archive and retrieved from the archive.

#### 4.1.14 Spare Parts Verification

Identify all spare parts with minimum quantity and location.

#### 4.2 Operational Qualification

#### 4.2.1 System Devices Verification

The objective of this verification is to confirm that the system hardware components operate properly by verifying that the system starts up without errors.

#### 4.2.2 System Security Verification

This section will challenge the documented security functionality of system and verify that unauthorized users will not be able to gain access to the system.

#### 4.2.3 System Calibration

This test will verify that all critical components of the system, which can be calibrated, have documented evidence of current certification.

#### 4.2.4 Power Failure and Emergency Cut-off Verification

This test will verify that the system is capable of retaining system-operating parameters following a simulated power failure.

#### 4.2.5 Input / Output Verification

This section will challenge the input / output configuration of the Honeywell MiniTrend V5 Recorder.

#### 4.2.6 Custom Verification

This section will challenge any customization of the Honeywell MiniTrend V5 Recorder. Included in this test where applicable will be Custom Screens.

#### 4.2.7 21 CFR § 11 Compliance

Verify that the Honeywell MiniTrend V5 Paperless Recorder system meets requirements in regards to electronic record.

# 4.2.8 Support Software - TrendViewer, TrendManager Pro and Screen Designer

Test forms will only be included with the purchase of these options. This test will verify the functionality of TrendManager Pro and Screen Designer Software.

#### 4.2.9 Validation Test Equipment and Calibration

Validation test equipment required to conduct validation testing will be properly documented along with the appropriate calibration information.

# **5.0 Ongoing Evaluation**

Any modifications to Honeywell MiniTrend V5 recorder hardware and software components must be documented and approved in accordance with change control procedures (\_\_\_\_\_]).

Document Number

This change control procedure is designed to ensure that any changes to the system are documented, evaluated, and approved by the same departments that approved the plan and this qualification protocol.

# Protocol End

#### Protocol Amendment and Deviation Summary

Page \_\_\_\_ of \_\_\_\_

- 1. Number deviations or amendments consecutively, as applicable to this protocol.
- 2. Document deviations thoroughly, including corrective actions. If re-tests were performed, include all original test records with the validation package.
- 3. Document amendments, and attach the acceptance criteria approved prior to execution of the amendment.

#### **Status Log**

Deviation Number	Description	Verified /date)	by	(Init.

<b>Protocol Amend</b>	ment and Dev	iation Record		
			Pag	eof
Number assigned to this	deviation or an	nendment:		
Date:	Reported	by:		
Date/Time/Location	that	Deviation	was	observed:
Affected protocol section	1:			
Describe nature of deviat	tion or Amendn	nent (Be Specific):		
Immediate Action Taken	:			
Long Term (Remedial) A	Action Directed	by:		

Describe Actions or Resolution and Justification:

Was a re-test necessary due to the deviation or amendment? (Y/N)

Validation Manager: (Init/date):

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Installation Verification						
Attach.	Protocol	Task	Acceptance Criteria	Responsible	Date Completed	
6.1.1	4.1.1	Drawing and Diagrams	All drawings and diagrams have been reviewed and match the actual system.		Completed	
6.1.2	4.1.2	Standard Operating Procedures	All identified procedures stated in purpose exist in minimum draft form.			
6.1.3	4.1.3	Manuals and Miscellaneous Documents	All documentation has been identified and is stored in a central location.			
6.1.4	4.1.4	Inventory of Components	All installed hardware components reflect expected hardware components based on model number.			
			Computer (If Applicable)			
			Computer hardware satisfies manufacturer requirements.			
6.1.5	4.1.5	Configuration Verification	Approved configuration specification matches installed recorder.			
6.1.6	4.1.6	Operating Environment	The operating environment requirements have been met.			
6.1.7	4.1.7	Training and Documentation	All personnel responsible for operation of system have documented evidence of required skills and training			
6.1.8	4.1.8	Service Contract / Support Agreement	A Service Contract / Support agreement is in place for the recorder			
6.1.9	4.1.9	Contingency and Disaster Plans	A contingency and disaster recovery plan exists that describes measures to be taken in the event of a disaster			
6.1.10	4.1.10	Backup and Storage Procedure	A backup and storage procedure exists and is available to authorized personnel and to that a backup and storage records are properly identified and complete.			

	Installation Verification					
Attach. #	Protocol Section	Task	Acceptance Criteria	Responsible	Date Completed	
6.1.11	4.1.11	Uninterruptible Power Source Verification	An Uninterruptible Power Source (or equivalent) is installed.			
6.1.12	4.1.12	Physical Security	Adequate security is in place.			
6.1.13	4.1.13	Data File Archiving, Storage and Retrieval Verification	Archive data is successfully stored on media and retrieved in external software program			
6.1.14	4.1.14	Spare Parts Verification	All spare parts are identified with minimum quantity and location.			

Operational	Verification
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Attach. #	Protocol Section	Task	Acceptance Criteria	Responsible Party	Date Completed
6.2.1	4.2.1	System Devices Verification	System restarts according to the manufacturer's specifications		
6.2.2	4.2.2	System Security Verification	System security performance is in accordance with manufacturers specifications		
6.2.3	4.2.3	System Calibration	All instrument requiring calibration have been placed into a calibration program and there is a current certification in effect		
6.2.4	4.2.4	Power Failure and Emergency Cut Off Verification	The recorder remains operational with a power failure and that power may be disconnected by means of emergency disconnect switch.		
6.2.5	4.2.5	Input / Output Verification	All installed I/O performs in accordance to user configuration.		
6.2.6	4.2.6	Custom Verification	All alarms, custom screens, graphs, events and custom Excel graphs/reports have been identified and verified to work in accordance to user specifications.		
6.2.7	4.2.7	21 CFR § 11 Compliance	System complies with regulatory requirement in regards to electronic records.		
6.2.8	4.2.8	Support Software TrendViewer, TrendManager Pro, Screen Designer	Support software performs in accordance to manufacturers specifications		
6.2.9	4.2.9	Validation Test Equipment and Calibration	All test equipment used during validation has current NIST certification.		

## 6.1.1 Drawings and Diagrams

Purpose	Review and record all drawings and/or diagrams associated with Honeywell MiniTrend V5 Recorder.				
Acceptance Criteria	All drawings and system.	diagrams have been review	red and match the actual		
Procedure	Complete table be Mark all empty bl	low in its entirety. ocks with N/A.			
Description	Date/ RevisionLocationTest Result Pass/FailInitial Date				
Comments:					

Performed By:

Date:

Verified By: \_\_\_\_\_

## 6.1.2 Standard Operating Procedures

Use copy of this page if additional spaces are required.

Purpose	To record all SOPs (i.e., system-specific user and administrative operations procedures, access control and security, system startup/shutdown, training, backup/restore and archiving, performance monitoring, incident reporting and analysis, hardware maintenance, disaster recovery, and change control) associated with the hardware and network components of Honeywell MiniTrend V5 Recorder.					
Acceptance Criteria	All identified pr	roced	ures stated in purpose exist in r	ninimum draft form.		
Procedure	1. Con	mplet	e table below in its entirety.			
	2. Ma	rk all	empty blocks with N/A.			
Title/ ID Number	Approval I Revision	Date/	Location	Test Result Pass/Fail Initial Date		
Comments:						

Performed By:

Date: \_\_\_\_\_

Verified By:

Date:

#### 6.1.3 Manuals and Miscellaneous Documents

Purpose	To record the documentation, such as manuals and all other applicable documentation such as: vendor audits, purchase order requisition, etc. for the Honeywell MiniTrend V5 Recorder hardware and software components.	
Acceptance Criteria	All documentation has been identified and is stored in a central location.	
Procedure	<ol> <li>Complete table belo</li> <li>Mark all empty bloc</li> </ol>	w in its entirety. ks with N/A.
Manual Title/Number	Location	Test Result Pass/Fail Initial Date
Comments:		

Performed By:

Date: \_\_\_\_\_

Verified By: \_\_\_\_\_

Date:

# 6.1.4 Inventory of Hardware Components

Purpose	Recorder	
	To ensure that installed recorder hardware components reflect model number specification.	
	Computer	
	To identify installed computer components and verify manufacturer specifications are met.	
Acceptance Criteria	Recorder	
	To identify installed computer components and verify manufacturer specifications are met. Installed recorder hardware components reflect expected hardware components based on model number.	
	Computer	
	Computer hardware satisfies manufacturer requirements.	
Procedure	<ol> <li>Document Hardware components of Honeywell MiniTrend V5 Recorder in the Honeywell MiniTrend V5 Actual Hardware Configuration Table.</li> </ol>	
	2. Compare hardware components recorded to Expected Results Table corresponding to the Model Number recorded in Step 1.	
	3. Model Number may contain numeric values different than documented model number due to non-hardware options. These numbers are identified by an underline in the documented model number.	
	<ol> <li>Reference MiniTrend V5 DC rear panel Figure 3.2 and 3.2a for card/slot reference. Slot Configuration identified on Expected Results Table reflect factory default configuration. Identify any deviations and refer to manufacturers manual for accepted alternate slot.</li> </ol>	
	<ol> <li>Complete Computer Component Table in its entirety. Applicable only if support software installed, i.e. TrendViewer, TrendManager Pro and Screen Designer. Use copy of form for each installed workstation with access to any of the above listed software.</li> </ol>	

Performed By:	Date:	
Verified By:	Date:	

#### 6.14. Figures 3.2 and 3.2a



#### Minitrend V5 DC rear panel

 Performed By:
 \_\_\_\_\_

 Verified By:
 \_\_\_\_\_

 Date:
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Page \_\_\_\_of \_\_\_\_ Protocol Attachment Document # 103

	6.1.4 Expected Results Table					
Uı	nderlined positions in r	nodel number may diff	er than actual model nu	mber but do not affect pl	hysical hardware compo	nent expectation.
Model Numbeı	TVMI-ML-40- <u>000</u> -0 <u>00</u> -010- 	TVMI- ML-40- <u>000</u> -T <u>00</u> - 010 TVMI- ML-40- <u>000</u> -E <u>00</u> - 010 TVMI- ML-40- <u>000</u> -A <u>00</u> - 010 TVMI- ML-40- <u>000</u> -M <u>00</u> - 010	TVMI- BF-40- <u>000</u> -0 <u>00</u> -010- 	TVMI- BF-40- <u>000</u> -0 <u>00</u> -F10- 	TVMI-BF-40- <u>000</u> -T <u>00</u> -F10 TVMI-BF-40- <u>000</u> -E <u>00</u> -F10 TVMI-BF-40- <u>000</u> -A <u>00</u> -F10 TVMI-BF-40- <u>000</u> -M <u>00</u> -F10	TVMI-BF-40- <u>000</u> -T <u>00</u> -010 TVMI-BF-40- <u>000</u> -E <u>00</u> -010 TVMI-BF-40- <u>000</u> -A <u>00</u> -010 TVMI-BF-40- <u>000</u> -M <u>00</u> -010
Slot A	Linear Input Card w/ 8 Channels	Linear Input Card w/ 8 Channels	Standard Input Card w/ 8 Channels	Standard Input Card w/ 8 Channels	Standard Input Card w/ 8 Channels	Standard Input Card w/ 8 Channels
Slot B:	Linear Input Card w/ 8 Channels	Linear Input Card w/ 8 Channels	Standard Input Card w/ 8 Channels	Standard Input Card w/ 8 Channels	Standard Input Card w/ 8 Channels	Standard Input Card w/ 8 Channels
Slot C:	None	Communication Card	None	None	Communication Card	Communication Card
Slot D:	Alarm Card with 4 relay outputs	Alarm Card with 4 relay outputs	Alarm Card with 4 relay outputs	Alarm Card with 4 relay outputs	Alarm Card with 4 relay outputs	Alarm Card with 4 relay outputs
PCMCI	PCMCIA	PCMCIA	PCMCIA	PCMCIA	PCMCIA	PCMCIA
Disk				Disk	Disk	

Performed By: \_\_\_\_\_

Date: \_\_\_\_\_

Verified By:

Date:

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6.1.4 System Identification		
	Actual	
System		
Identification Number		
Location/Room		
Manufacturer		
Model Number		

6.1.4 Honeywell MiniTrend V5 Actual Hardware Configuration Table			
	Actual	Performed by:	Pass / Fail
Slot A			
Slot B			
Slot C			
Slot D			
PCMCIA Disk			

Performed By:	 Date:	
-		

Verified By: \_\_\_\_\_

Protocol Attachment Document # 103

6.1.4 Computer Component Table Page of			
Item	Specification	As Installed	
Asset Tag Number			
Location			
Intended Use			
Manufacturer Requirement	Installed Components	Meets Requirements	
		(Circle One)	
200 MHz Pentium	Processor Speed:	YES NO	
32MB or more RAM (64 MB recommended)	MB RAM:	YES NO	
Microsoft® Windows 95,98, 2000 or Windows NT ver. 4.0 or Service pack 3 (onwards)	Windows:	YES NO	
TrendViewer			
TrendManager Pro		N/A	
Screen Designer			
MS-Windows compatible pointing	Manufacturer:	YES NO	
device	Serial Number:		
Disk	Manufacturer:	YES NO	
Type: 3.5", Zip, other	Туре:		
PCMCIA Drive	Manufacturer:	YES NO	
(If Applicable)	Serial Number:		
CD-ROM drive	Manufacturer:	YES NO	
	Serial Number:		
Video Monitor capable of 1024x768	Manufacturer:	YES NO	
	Serial Number:		

Performed By:

Date:	
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Date: \_\_\_\_\_

Verified By: \_\_\_\_\_

#### 6.1.5 Configuration Verification

Purpose	To ensure the approved configuration specification reflects as installed configuration on MiniTrend recorder.	
Acceptance Criteria	Identify Approved Configuration Specification: Actual recorder configuration is as specified on Customer specific Configuration Specification.	
Procedure	<ol> <li>Complete MiniTrend Configuration Table in its entirety</li> <li>Attach copies of TrendManager Pro Configuration report behind each applicable table. i.e. Pen Configuration Report behind Pen Tables. Complete Configuration Table by referencing actual recorder settings. Expected Reports include: TrendView Recorder Setup: Pens, General, Analogs and Events.</li> <li>Compare documented configuration with Approved Configuration Specification.</li> </ol>	



\_\_\_\_\_

Document #:103

6 1 5 MiniTrend Configuration Table (Continued)		
General Sub Menu Screen		
	Ceneral Language English (UK) ► Name Pump S Desc Statio ID Number 4444 Default Drive Disk ► Set Time Screen ► Options Code ► Password ► Factor v ►	
Category	As Configured	Performed By
Screen Brightness		
Screen Saver		
Screen Timeout		
Screen Chart Paper		
General Sub Menu Password	Operation     English CUK0       Name     Statio       Desc     Pume V       Diskuber     nool       Destation     Greinern       Destation     Greinern       Destation     Vitv       Gereinern     Gereinern	
Category	As Configured	Performed By
Password Enabled / Disabled		
Users	User1:	
Place N/A if user not	User2:	
configured. Indicate user	User3:	
nume unu uccess.	User4:	
	User5:	
	User6:	
	User7:	
	User8:	
	User9:	
	User10:	
	User11:	
	User12:	
	User13:	
	User14:	
	User15:	
	User16:	
	User17:	
	User18:	
	User19:	
	User20:	
Performed By:		Date:

Verified By:

Date: \_\_\_\_\_

6.1.5 MiniTrend Configuration Table (Continued)								
General Sub Menu Comms (Comms or Modbus/Profibus Comms menu will appear)								
General Language E Name T Desc T ID Number 0 Default Drive D Set Time Screen Options Code Password Comms Factory	nalish (UK)   V5 Re V5 Re 1200 isk V Ethernet R5232 R5485 R5232 (Front) Subnet Ma Sockets Email	IP Resolution FIXED * BOOTP DHOP						
Category	As Configured	Performed By						
Applicable with Ethernet selection only. Enter N/A if Ethernet option not purchased.	IP Resolution IP Address Default Gateway Subnet Mask Protocols Sockets Email							
RS232 Applicable with RS232 selection only. Enter N/A if RS232 option not purchased.	Data Rate Date Bits Parity Stop Bits Protocol							
RS485 Applicable with RS485 selection only. Enter N/A if RS485 option not purchased.	Data Rate         Data Bits         Parity         Stop Bits         Line Type         Protocol							
RS232 (Front) Applicable with RS232 (Front) selection only. Enter N/A if RS232 (Front) option not purchased.	Data Rate Data Bits Parity Stop Bits Protocol							

Performed By:

Date:

Verified By:

Date: \_\_\_\_\_

6.1.5 MiniTrend Configuration Table (Continued)							
General Sub Menu Modbus/Profibus Card Comms Card 2 (Comms or Modbus/Profibus Comms menu will appear)							
	GeneralFieldbuLanguageEnglish (UK) ►NameStatioDescPump tID Number0001Default Drive Disk►Set Time▼Screen►Options Code▼Password►Factory►	us channel IS ENET P BUS P					
Category	As Configured	Performed By					
Modbus	Enable	· · · · ·					
Applicable with	Address						
Modbus selection	Baud Rate						
only. Enter N/A if	Byte Format Option						
Modbus option not	Line Turn-Around						
purchased.	Tx Invalid Time						
DeviceNet							
Profibus	Enable						
Applicable with	Address						
Profibus selection	Acyclic buffer						
only. Enter N/A if	Cyclic Input Buffer						
Profibus option not	Cyclic Output Buffer						
purchased							
	General       Factor 9         Language       English (UK) >         Name       Events         Desc       oons         ID Number       4444         Default Drive Disk       >         Set Time       +         Screen       >         Options Code       +         Password       >         Factor 9       >	Input F Output F Prts F UP					
Category	As Configured	Performed By					
Calibrate Input	Slot A						
	Slot B						
	Slot Al						
D :	Slot B1						
Drives	Floppy						
	PC Card						
Comms Ports	Ethernet						
	RS485						
	RS232						

Performed By:	_ Date:
Verified By:	Date:

Installation/Operational Qualification Honeywell MiniTrend V5 Recorder SN:0123456 **Protocol Attachment** 

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**Document** # 103

Sub Menu Analog In																
Category /Name	Name	Enabled	Units	Туре	Range	Inp 0	Inp Span	Cond	Sqrt Extr	Eng Zero	Eng Span	T/ C	RT	Temp Cal	Tie To	Sampling
Enter Input Name																
A1																
A2																
A3																
A4																
A5																
A6																
A7																
A8																
A9																
A10																
A11																
A12																

Performed By: \_\_\_\_\_

Date: \_\_\_\_\_

Verified By:

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**Protocol Attachment** 

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	Sub Menu Analog In (Continued)															
Category /Name Enter Input Name	Name	Enabled	Units	Туре	Range	Inp 0	Inp Span	Cond	Sqrt Extr	Eng Zero	Eng Span	T/ C	RT	Temp Cal	Tie To	Sampling
A13																
A14																
A15																
A16																

Performed By: \_\_\_\_\_

Date: \_\_\_\_\_

Verified By: \_\_\_\_\_

Date: \_\_\_\_\_

Sub Menu Pens						
Pen 1						
ENABLED						
TAG						
DESCRIPTION						

Maths	Scale	Alarms	Totalizer	Logging
Expression:	Units:	Alarm #:	Enabled:	Normal Enabled:
Pen:	Top:	Enabled:	Normal Type:	
Analog In:	Bottom:	Tag:	Normal Method:	
Digital In :	Scale Fact:	Туре:	Units:	Normal Rate:
Relay:	Format:	Level:	Factor:	Device:
Total:	Divs:	Log Alarm:	Format:	
Counter:		Relay Enable:	Limit Range:	
Content:		Relays:	Min:	
Complex Variable:		Hysteresis:	Max:	
		Damping:	Carry On Rollover:	

Performed By: Date: \_\_\_\_\_ Verified By: \_\_\_\_\_ Date: \_\_\_\_\_

Sub Menu Pens								
Pen 2								
ENABLED								
TAG								
DESCRIPTION								

MATHS	SCALE	ALARMS	TOTALIZER	LOGGING	
Expression:	Units:	Alarm #:	Enabled:	Normal Enabled:	
Pen:	Тор:	Enabled:	Enabled: Ignore Back Flow:		
Analog In:	Bottom:	Tag:	Tag: Standard Form:		
Digital In :	Scale Fact:	Туре:	Units:	Normal Rate:	
Relay:	Format:	Level:	Factor:	Device:	
Total:	Divs:	Log Alarm:	Format:		
Counter:		Relay Enable:	Limit Range:		
Content:		Relays:	Min:		
Complex Variable:		Hysteresis:	Max:		
		Damping:	Carry On Rollover:		

Performed By:

Date: \_\_\_\_\_

Verified By: \_\_\_\_\_

Date: \_\_\_\_\_
Sub Menu Pens			
Pen 3			
ENABLED			
TAG			
DESCRIPTION			

MATHS	SCALE	ALARMS	TOTALIZER	LOGGING
Expression:	Units:	Alarm #:	Enabled:	Normal Enabled:
Pen:	Тор:	Enabled:	Ignore Back Flow:	Normal Type:
Analog In:	Bottom:	Tag:	Standard Form:	Normal Method:
Digital In :	Scale Fact:	Туре:	Units:	Normal Rate:
Relay:	Format:	Level:	Factor:	Device:
Total:	Divs:	Log Alarm:	Format:	
Counter:		Relay Enable:	Limit Range:	
Content:		Relays:	Min:	
Complex Variable:		Hysteresis:	Max:	
		Damping:	Carry On Rollover:	

Performed By:

Date: \_\_\_\_\_

Verified By: \_\_\_\_\_

Sub Menu Pens			
Pen 4			
ENABLED			
TAG			
DESCRIPTION			

MATHS	SCALE	ALARMS	TOTALIZER	LOGGING
Expression:	Units:	Alarm #:	Enabled:	Normal Enabled:
Pen:	Тор:	Enabled:	Ignore Back Flow:	Normal Type:
Analog In:	Bottom:	Tag:	Standard Form:	Normal Method:
Digital In :	Scale Fact:	Туре:	Units:	Normal Rate:
Relay:	Format:	Level:	Factor:	Device:
Total:	Divs:	Log Alarm:	Format:	
Counter:		Relay Enable:	Limit Range:	
Content:		Relays:	Min:	
Complex Variable:		Hysteresis:	Max:	
		Damping:	Carry On Rollover:	

Performed By:

Date: \_\_\_\_\_

Verified By:

Sub Menu Pens			
Pen 5			
ENABLED			
TAG			
DESCRIPTION			

MATHS	SCALE	ALARMS	TOTALIZER	LOGGING
Expression:	Units:	Alarm #:	Enabled:	Normal Enabled:
Pen:	Тор:	Enabled:	Ignore Back Flow:	Normal Type:
Analog In:	Bottom:	Tag:	Standard Form:	Normal Method:
Digital In :	Scale Fact:	Туре:	Units:	Normal Rate:
Relay:	Format:	Level:	Factor:	Device:
Total:	Divs:	Log Alarm:	Format:	
Counter:		Relay Enable:	Limit Range:	
Content:		Relays:	Min:	
Complex Variable:		Hysteresis:	Max:	
		Damping:	Carry On Rollover:	

Performed By:

Date: \_\_\_\_\_

Verified By: \_\_\_\_\_

Sub Menu Pens			
Pen 6			
ENABLED			
TAG			
DESCRIPTION			

MATHS	SCALE	ALARMS	TOTALIZER	LOGGING
Expression:	Units:	Alarm #:	Enabled:	Normal Enabled:
Pen:	Top:	Enabled:	Ignore Back Flow:	Normal Type:
Analog In:	Bottom:	Tag:	Standard Form:	Normal Method:
Digital In :	Scale Fact:	Туре:	Units:	Normal Rate:
Relay:	Format:	Level:	Factor:	Device:
Total:	Divs:	Log Alarm:	Format:	
Counter:		Relay Enable:	Limit Range:	
Content:		Relays:	Min:	
Complex Variable:		Hysteresis:	Max:	
		Damping:	Carry On Rollover:	

Performed By:

Date: \_\_\_\_\_

Verified By: \_\_\_\_\_

Sub Menu Pens			
Pen 7			
ENABLED			
TAG			
DESCRIPTION			

MATHS	SCALE	ALARMS	TOTALIZER	LOGGING
Expression:	Units:	Alarm #:	Enabled:	Normal Enabled:
Pen:	Тор:	Enabled:	Ignore Back Flow:	Normal Type:
Analog In:	Bottom:	Tag:	Standard Form:	Normal Method:
Digital In :	Scale Fact:	Туре:	Units:	Normal Rate:
Relay:	Format:	Level:	Factor:	Device:
Total:	Divs:	Log Alarm:	Format:	
Counter:		Relay Enable:	Limit Range:	
Content:		Relays:	Min:	
Complex Variable:		Hysteresis:	Max:	
		Damping:	Carry On Rollover:	

Performed By:

Date:

Verified By: \_\_\_\_\_

Sub Menu Pens			
Pen 8			
ENABLED			
TAG			
DESCRIPTION			

MATHS	SCALE	ALARMS	TOTALIZER	LOGGING
Expression:	Units:	Alarm #:	Enabled:	Normal Enabled:
Pen:	Тор:	Enabled:	Ignore Back Flow:	Normal Type:
Analog In:	Bottom:	Tag:	Standard Form:	Normal Method:
Digital In :	Scale Fact:	Туре:	Units:	Normal Rate:
Relay:	Format:	Level:	Factor:	Device:
Total:	Divs:	Log Alarm:	Format:	
Counter:		Relay Enable:	Limit Range:	
Content:		Relays:	Min:	
Complex Variable:		Hysteresis:	Max:	
		Damping:	Carry On Rollover:	

Performed By:

Date: \_\_\_\_\_

Verified By: \_\_\_\_\_

Sub Menu Pens			
Pen 9			
ENABLED			
TAG			
DESCRIPTION			

MATHS	SCALE	ALARMS	TOTALIZER	LOGGING
Expression:	Units:	Alarm #:	Enabled:	Normal Enabled:
Pen:	Тор:	Enabled:	Ignore Back Flow:	Normal Type:
Analog In:	Bottom:	Tag:	Standard Form:	Normal Method:
Digital In :	Scale Fact:	Туре:	Units:	Normal Rate:
Relay:	Format:	Level:	Factor:	Device:
Total:	Divs:	Log Alarm:	Format:	
Counter:		Relay Enable:	Limit Range:	
Content:		Relays:	Min:	
Complex Variable:		Hysteresis:	Max:	
		Damping:	Carry On Rollover:	

Performed By:

Date: \_\_\_\_\_

Verified By: \_\_\_\_\_

Sub Menu Pens			
Pen 10			
ENABLED			
TAG			
DESCRIPTION			

MATHS	SCALE	ALARMS	TOTALIZER	LOGGING
Expression:	Units:	Alarm #:	Enabled:	Normal Enabled:
Pen:	Тор:	Enabled:	Ignore Back Flow:	Normal Type:
Analog In:	Bottom:	Tag:	Standard Form:	Normal Method:
Digital In :	Scale Fact:	Туре:	Units:	Normal Rate:
Relay:	Format:	Level:	Factor:	Device:
Total:	Divs:	Log Alarm:	Format:	
Counter:		Relay Enable:	Limit Range:	
Content:		Relays:	Min:	
Complex Variable:		Hysteresis:	Max:	
		Damping:	Carry On Rollover:	

Performed By:

Date: \_\_\_\_\_

Verified By: \_\_\_\_\_

Sub Menu Pens			
Pen 11			
ENABLED			
TAG			
DESCRIPTION			

MATHS	SCALE	ALARMS	TOTALIZER	LOGGING
Expression:	Units:	Alarm #:	Enabled:	Normal Enabled:
Pen:	Тор:	Enabled:	Ignore Back Flow:	Normal Type:
Analog In:	Bottom:	Tag:	Standard Form:	Normal Method:
Digital In :	Scale Fact:	Туре:	Units:	Normal Rate:
Relay:	Format:	Level:	Factor:	Device:
Total:	Divs:	Log Alarm:	Format:	
Counter:		Relay Enable:	Limit Range:	
Content:		Relays:	Min:	
Complex Variable:		Hysteresis:	Max:	
		Damping:	Carry On Rollover:	

Performed By:

Date:

Verified By: \_\_\_\_\_

Sub Menu Pens			
Pen 12			
ENABLED			
TAG			
DESCRIPTION			

MATHS	SCALE	ALARMS	TOTALIZER	LOGGING
Expression:	Units:	Alarm #:	Enabled:	Normal Enabled:
Pen:	Top:	Enabled:	Ignore Back Flow:	Normal Type:
Analog In:	Bottom:	Tag:	Standard Form:	Normal Method:
Digital In :	Scale Fact:	Туре:	Units:	Normal Rate:
Relay:	Format:	Level:	Factor:	Device:
Total:	Divs:	Log Alarm:	Format:	
Counter:		Relay Enable:	Limit Range:	
Content:		Relays:	Min:	
Complex Variable:		Hysteresis:	Max:	
		Damping:	Carry On Rollover:	

Performed By:

Date:

Verified By: \_\_\_\_\_

Sub Menu Pens			
Pen 13			
ENABLED			
TAG			
DESCRIPTION			

MATHS	SCALE	ALARMS	TOTALIZER	LOGGING
Expression:	Units:	Alarm #:	Enabled:	Normal Enabled:
Pen:	Тор:	Enabled:	Ignore Back Flow:	Normal Type:
Analog In:	Bottom:	Tag:	Standard Form:	Normal Method:
Digital In :	Scale Fact:	Туре:	Units:	Normal Rate:
Relay:	Format:	Level:	Factor:	Device:
Total:	Divs:	Log Alarm:	Format:	
Counter:	-	Relay Enable:	Limit Range:	
Content:		Relays:	Min:	
Complex Variable:		Hysteresis:	Max:	
		Damping:	Carry On Rollover:	

Performed By:

Date:

Verified By: \_\_\_\_\_

Sub Menu Pens			
Pen 14			
ENABLED			
TAG			
DESCRIPTION			

MATHS	SCALE	ALARMS	TOTALIZER	LOGGING
Expression:	Units:	Alarm #:	Enabled:	Normal Enabled:
Pen:	Top:	Enabled:	Ignore Back Flow:	Normal Type:
Analog In:	Bottom:	Tag:	Standard Form:	Normal Method:
Digital In :	Scale Fact:	Туре:	Units:	Normal Rate:
Relay:	Format:	Level:	Factor:	Device:
Total:	Divs:	Log Alarm:	Format:	
Counter:		Relay Enable:	Limit Range:	
Content:		Relays:	Min:	
Complex Variable:		Hysteresis:	Max:	
		Damping:	Carry On Rollover:	

Performed By:

Date:

Verified By: \_\_\_\_\_

Sub Menu Pens			
Pen 15			
ENABLED			
TAG			
DESCRIPTION			

MATHS	SCALE	ALARMS	TOTALIZER	LOGGING
Expression:	Units:	Alarm #:	Enabled:	Normal Enabled:
Pen:	Top:	Enabled:	Ignore Back Flow:	Normal Type:
Analog In:	Bottom:	Tag:	Standard Form:	Normal Method:
Digital In :	Scale Fact:	Туре:	Units:	Normal Rate:
Relay:	Format:	Level:	Factor:	Device:
Total:	Divs:	Log Alarm:	Format:	
Counter:		Relay Enable:	Limit Range:	
Content:		Relays:	Min:	
Complex Variable:		Hysteresis:	Max:	
	-	Damping:	Carry On Rollover:	

Performed By:

Date:

Verified By: \_\_\_\_\_

Sub Menu Pens			
Pen 16			
ENABLED			
TAG			
DESCRIPTION			

MATHS	SCALE	ALARMS	TOTALIZER	LOGGING
Expression:	Units:	Alarm #:	Enabled:	Normal Enabled:
Pen:	Тор:	Enabled:	Ignore Back Flow:	Normal Type:
Analog In:	Bottom:	Tag:	Standard Form:	Normal Method:
Digital In :	Scale Fact:	Туре:	Units:	Normal Rate:
Relay:	Format:	Level:	Factor:	Device:
Total:	Divs:	Log Alarm:	Format:	
Counter:	-	Relay Enable:	Limit Range:	
Content:		Relays:	Min:	
Complex Variable:		Hysteresis:	Max:	
		Damping:	Carry On Rollover:	

Performed By:

Date:

Verified By: \_\_\_\_\_

# Sub Menu Relays/Digital



Channel	Label	On State	Off State	As Input	As Output	Fail Safe	Log Digital
Channel 1							
Channel 2							
Channel 3							
Channel 4							

Performed By:

Date:

Verified By:

6.1.5 MiniTrend Configuration Table (Continued)			
Main Menu Recording Enabled Log To Disk Eject Disk Save Data & Eject Disk Log To PC Card Prepare to Remove PC Card Validate Disk			
Category	As Configured	Performed By	
Enabled			
Log To Disk			

Main Menu Layout	Menu       Setup       Screen 1       Previous         Setup       Screen 1       Screen 2       Enabled         Totals       Screen 3       Enabled       Enabled         Counters       Screen 4       Label       Method         Chanse Password       Screen 5       Method       Label       Channel 1         Lavout       Screen 6       Channel 1       Channel 3       Channel 3         About       Screen 9       Channel 4       Channel 4       Channel 5         Screen 10       Screen 10       Channel 5       Channel 5         Screen 10       Save Lavout       Channel 7       Channel 7	nfisuration Screen 3 Chart + Digitals ► P1 P2 P3 P4 P5 P6 P7 P8
Category	As Configured	Performed By
Screen 1	Enabled	
	Label	
	Method	
	Channel 1	
	Channel 2	
	Channel 3	
	Channel 4	
	Channel 5	
	Channel 6	
	Channel 7	
	Channel 8	
Performed By:	1	Date:
Verified By:		Date:

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6.1.5 MiniTrend Configuration Table (Continued)				
Category	As Configured	Performed By		
Screen 2	Enabled			
	Label			
	Method			
	Channel 1			
	Channel 2			
	Channel 3			
	Channel 4			
	Channel 5			
	Channel 6			
	Channel 7			
	Channel 8			

Performed By:	Date:	

Verified By: \_\_\_\_\_ Date: \_\_\_\_\_

6.1.5 MiniTrend Configuration Table (Continued)			
Category	As Configured	Performed By	
Screen 3	Enabled		
	Label		
	Method		
	Channel 1		
	Channel 2		
	Channel 3		
	Channel 4		
	Channel 5		
	Channel 6		
	Channel 7		
	Channel 8		
Screen 4	Enabled		
	Label		
	Method		
	Channel 1		
	Channel 2		
	Channel 3		
	Channel 4		
	Channel 5		
	Channel 6		
	Channel 7		
	Channel 8		
Performed By:		Date:	

Verified By: \_\_\_\_\_ Date: \_\_\_\_\_

6.1.5 MiniTrend Configuration Table (Continued)			
Category	As Configured	Performed By	
Screen 5	Enabled		
	Label		
	Method		
	Channel 1		
	Channel 2		
	Channel 3		
	Channel 4		
	Channel 5		
	Channel 6		
	Channel 7		
	Channel 8		
Screen 6	Enabled		
	Label		
	Method		
	Channel 1		
	Channel 2		
	Channel 3		
	Channel 4		
	Channel 5		
	Channel 6		
	Channel 7		
	Channel 8	]	

Performed By:

Date: \_\_\_\_\_

Verified By:

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6.1.5 MiniTrend Configuration Table (Continued)			
Category	As Configured	Performed By	
Screen 7	Enabled		
	Label		
	Method		
	Channel 1		
	Channel 2		
	Channel 3		
	Channel 4		
	Channel 5		
	Channel 6		
	Channel 7		
	Channel 8		
Screen 8	Enabled		
	Label		
	Method		
	Channel 1		
	Channel 2		
	Channel 3		
	Channel 4		
	Channel 5		
	Channel 6		
	Channel 7		
	Channel 8		

Performed By:

Date:

Verified By:

6.1.5 MiniTrend Configuration Table (Continued)			
Category	As Configured	Performed By	
Screen 9	Enabled		
	Label		
	Method		
	Channel 1		
	Channel 2		
	Channel 3		
	Channel 4		
	Channel 5		
	Channel 6		
	Channel 7		
	Channel 8		
Screen 10	Enabled		
	Label		
	Method		
	Channel 1		
	Channel 2		
	Channel 3		
	Channel 4		
	Channel 5		
	Channel 6		
	Channel 7		
	Channel 8		

Performed By:

Date:

Verified By:

6.1.5 Main Menu About				
Category	As Configured	Performed By		
Loader =				
Firmware =				
Serial Number				
Session				
Maths				
Totals				
Events				
ESS				
Custom Screens Attach a Screen Shot for each Custom Screen designed and annotate configuration. Label each Custom Screen Attachment 6.1.5-Custom Screen (1-XX) Sign and initial each screen Mimics Attach a Screen Shot for each Custom Screen designed and annotate configuration. WebServer				
F-Mail				
TrendBus				
ModBus				
Profibus				
# of Extra Pens				
Performed By:	·	Date:		
Verified By:		Date:		

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6.1.5 Additional Configuration Table
Category
Graphs
If Applicable: Identify each graph created on TrendManager Pro.
Graph Name
Category
Excel Graphs/Worksheet Identified any saved Excel template.
Performed By: Date:

Verified By:	Date:	

6.1.5Additional Configuration Table					
	Category				
	Events				
<ol> <li>Identify each configured event below or attach the TrendView recorder setup – Events report and label .6.1.5 Events. Label, initial and date each page.</li> </ol>					
2. Place single li	ne through table, mark N	N/A initial and date if re	ports are attached.		
Events Name					
Event Name	Cause	Effect	Marker/Counter/Email		

Actual Recorder configuration matches the customer specific Configuration Specification: Pass / Fail Initial / Date

 Performed By:
 Date:

 Verified By:
 Date:

# 6.1.6 Operating Environment

Purpose	To ensure that the systems operating environment requirements have been met.			
Acceptance Criteria	The operating environment requirements have been met.			
Procedure	Complete below table in its entirety to verify that the manufacturers operating environment requirements have been met. (Temperature, Humidity, Power, etc.)			
Parameter	Expected Results	Actual Results	Pass/ Fail	Initial / Date
Case/Mounting	MN: TVMI-XX-XX-XXX-XXX-0XXXXX			
	Standard Panel Mounting			
	MN: TVMI-XX-XX-XXX-XXX-CXXXXX			
	Nema4/IP65 Cover			
	MN: TVMI-XX-XX-XXX-XXX-PXXXXX			
	Portable			
Power Voltage	MN: TVMI-XX-XX-XXX-X0X			
r on or volume	90 - 264 VAC			
	MN: TVMI-XX-XX-XXX-X2X			
	24 VAC			
Ambient Temperature	0°C to 50°C			
Ambient	10% to 90%			
Humidity	(non-condensing)			
Comments:				

Performed By:	 Date:	

Verified By: \_\_\_\_\_

Date: \_\_\_\_\_

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# 6.1.7 Training and Documentation

Purpose	Verify that all training material for the Honeywell Trendview V5 Recorder is accessible, including but not limited to (Standard Operating Procedure, GMP Training, etc.).				
Acceptance Criteria	Identified tr	aining material is av	vailable and current	to installed syst	tem.
Procedure	1. Doc	cument title(s) of red	quired training cour	ses.	
	2. Con	nplete Training Tab	le in its entirety.		
	3. Plac	ce N/A, initial and d	ate for any unused	spaces.	
Course Ti	tles	Training Mater Revi	rial - Location - sion	Pass/ Fail	Initial / Date
Identify training c information:	ourses requi	red for each of the	e user levels or ide	entify SOP whi	ch details this
ENG -			TECHNICIAN -		
SUPERVISOR -			OPERATOR -		
Comments:			I		
Performed By:				Date:	
Verified By:				Date:	

# 6.1.8 Service Contract/Support Agreement

Purpose	Review the existence of a Service Contract / Support agreement.		
Acceptance Criteria	A Service Contract / Support agreement is in place for the recorder.		
Procedure	Complete Table in its entirety.		
Agreemen	Agreement Number Pass/ Fail		
		Initial / Date	
Comments:			

Performed By:	 Date:	

Verified By:

### 6.1.9 Contingency and Disaster Recovery Plans

Purpose	To ensure that a contingency and disaster recovery plan exists that describes measures to be taken in the event of a disaster.				
Acceptance Criteria	A contining the e	ngency and disaste vent of a disaster.	r recovery plan exists that descri	bes measures to be taken	
Procedure	<ol> <li>Verify that a contingency and disaster recovery plan exists that describes measures to be taken in the event of a disaster.</li> <li>The plan is to be inspected and reviewed to ensure that they are complete, current, and accessible to responsible personnel.</li> </ol>				
Plan Document Number		Approved (Yes or No)	LocationPass/FailInitial Date		
Comments:					

Performed By: \_\_\_\_\_

Date:

Verified By:

# 6.1.10 Backup and Storage Procedures

Purpose	To ensure that a backup and storage procedure exists and is available to authorized personnel and to ensure that a backup and storage records are properly identified, current and complete.					
Acceptance Criteria	A back to that a	up and storage produced a backup and storage	cedure exists and is available to a ge records are properly identified	uthorized personnel and and complete.		
Procedure	<ol> <li>Verify that a backup and storage procedure exists and is available to authorized personnel.</li> <li>Ensure that a current backup of recorder configuration has been performed and in generality and support identified.</li> </ol>					
			The second se			
Procedure Docu	ment	Approved	Location	Pass/Fail		
Number		(Yes or No)		Initial Date		
Comments:			·			

MiniTrend Optional Software Packages						
Software Package	Version/Release	Backup Location				
Trendviewer						
Trend Manager Pro						
Screen Designer						

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Verified By:

Performed	By:
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Date:			
Date:			

### 6.1.11 Uninterruptible Power Source

21CFR 11 requires ". (a) The regulations in this part set forth the criteria under which the agency considers **electronic** records, **electronic** signatures, and handwritten signatures executed to **electronic** records to be trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper". To comply with statement power should be uninterrupted to provide a trustworthy, reliable system.

Purpose	To document the uninterrupted power source which is provided to the Trendview system providing a trustworthy and reliable data collection system.			
Acceptance Criteria	An Uninterruptible Power Source (or e documented in table below.	quivalent) is installed and		
Procedure	1. Complete below table in its ent	irety.		
	2. Mark N/A for all non-applicable	le blocks.		
	Installed Specifications	Performed By Initial/Date		
Identification Number				
Location/Room				
Manufacturer				
Model Number				
Maximum Voltage				
Maximum Amperage				
Cycles				
Disconnect Switch Location	In close proximity to the recorder, and within easy reach of the operator			
Disconnect Switch Marking	Must be clearly marked,			
Comments:				

Test Result Pass/Fail: \_\_\_\_\_ Initial/Date: \_\_\_\_\_

Performed By:

Date:

Verified By:

# 6.1.12 Physical Security

21CFR 11 requires "Closed system means an environment in which system access is controlled by persons who are responsible for the content of electronic records that are on the system." Draw a single line through all blank lines. Mark N/A, Initial and Date.

Purpose	To ensure that the environment in which system is installed controls access.
Acceptance Criteria	Adequate security is in place.
Procedure	List below physical security details including, security guards, locked doors, software security, locked cabinets and any other security features.
	Security Features
Comments:	
Test Results Pa	ss/Fail: Initial/Date:

Performed By:	Date:	
Verified By:	Date:	

# 6.1.13 Data File Archiving, Storage, and Retrieval Verification

Purpose	Document that data can be stored to the archive and retrieved from the archive.			
Acceptance Criteria	Archive data is successfully stored on media and retrieved in external software program.			
Procedure	1. Obtain the appropriate blank data storage media(s) as applies to installed device model number.			
	2. Enable Recording of data.			
	3. Install blank media in drive. Activate logging to disk.			
	4. Record Start Time:			
	5. Record End Time:			
	<ol> <li>Log data for minimum period of at least one minute more than collection time of least sampled input.</li> </ol>			
	7. Select Validate Disk to initiate the disk and check for any corruption.			
	<ol> <li>Select Save Data and Eject Disk. Remove disk and insert in drive i computer with TrendViewer software installed.</li> </ol>			
	9. Click on the picture of the record in TrendViewer.			
	10. The default location to import data from is A:. If you want to chan, this, click on the change button and locate the data for the recorder using the browser.			
	11. Click yes and wait for the bar to reach the right hand side of the import box or click cancel if it is taking too long. Note any warning messages will appear in the scrolling message window.			
	12. Click ok when the setup has finished to return.			
	13. A graph of the data from recorder will automatically appear.			
	14. Verify that data was collected for the time period identified in Step 4 and 5 and is available for viewing.			
	15. Use print function to print a graph of the data and label 6.1.13a.			
Data is viewable in TrendV Test Result Pass/Fail:	viewer application and matches time period identified.			
Comments:				

Performed By:

Date:

Reviewed By:

# 6.1.13 Data File Archiving, Storage, and Retrieval Verification (Continued)

Procedure	16. Enable Recording of data.
Trocourt	17. Install blank PCMCIA card in card slot.
	18. Activate logging to PCMCIA card
	19. Record Start Time:
	20. Record End Time:
	21. Log data for minimum period of at least one minute more than collection time of least sampled input.
	22. Select Validate Disk to initiate the disk and check for any corruption.
	23. Select Prepare to remove PC card to force recorder to save data from buffer to PCMCIA card.
	24. Remove card and insert in PCMCIA in computer with TrendViewer software installed.
	25. Click on the picture of the record in TrendViewer.
	26. The default location to import data from is A:. If you want to change this, click on the change button and locate the data for the recorder using the browser.
	27. Click yes and wait for the bar to reach the right hand side of the import box or click cancel if it is taking too long. Note any warning messages will appear in the scrolling message window. Document messages if applicable. Restart from Step 22.
	28. Click ok when the setup has finished to return.
	29. A graph of the data from the recorder will automatically appear.
	30. Verify that data was collected for time period identified in Step 19 and 20 and is available for viewing.
	31. Use print function to print a graph of the data and label 6.1.13b.
Data is viewable in Trend Test Result Pass/Fail:	Viewer application and matches the time period identified.
Comments:	

Performed By:

Date:

Reviewed By:

# 6.1.14 Recommended Spare Parts

Purpose		Identify spare parts and location.			
Acceptance	Criteria	All spare parts are identified with minimum quantity and location. I.E. Floppy, Cards, UPS, etc.			
Procedure		<ol> <li>Complete below table in its entirety.</li> <li>Document required quantity and location for all spare parts including manufacturers recommended spare listed below.</li> <li>Mark all blank spaces with N/A, Initial and Date.</li> </ol>			
Quantity	Part Number/I	Description.	Storage Location	Test Result Pass/Fail	
				Initial /Date	
Display Backligh recommends 1)		ht (Mfg			
Comments:	·			·	

 Date:	 	

Performed By:

Reviewed By:

### 6.2.1 System Devices Verification

The first screen displayed is the 'power up screen' shown below. This only appears for a short time before changing to the last screen selected before the unit is switched off or, on first power up, it will show the bars screen with any available pens. To change screen layout press the *Screen* button and use the wheel on the right of the keypad to scroll up and down the selection menu. When the screen required is highlighted, press the thumbwheel to select.

**NB.** The flag displayed in the top right corner of the screen indicates the initial default language.



Power up screen

Purpose	To ensure that the system restarts according to the manufacturer's specifications.			
Acceptance Criteria	System restarts according to the manufacturer's specifications.			
Procedure	<ol> <li>Document Screen Name which is displayed prior to powering off:</li> <li></li></ol>			
Expected Results		Actual Results	Pass/ Fail	Initial / Date
1 <sup>st</sup> screen displayed is Power up Screen				
Screen entered in Step 1 is returned as default				
Comments				

Performed By:	Date:
Verified By:	Date:

#### 6.2.2 System Security Verification

Purpose	Review all aspects of system security and verify system security performance is in accordance with manufacturers specifications.
Acceptance Criteria	System security performs in accordance with manufacturers specifications.
Procedure	Complete the below steps in their entirety.

Recorder security is performed with the assignment of passwords and user levels. The four User levels available are:

Engineer – Highest access to all levels, Supervisor, Technician, and Operator Supervisor –  $2^{nd}$  highest level including Technician and Operator access Technician –  $3^{rd}$  level including Operator access Operator –  $4^{th}$  and lowest level of access

There are five setup screens, which can be protected from users. Access to these screens can be assigned using the Protect and Protect From menus.

System allows up to 20 different users. Passwords can be duplicated. The Administrator cannot access the passwords for other users. If the user does forget the password the user must be deleted from the recorder and start again.

MAINMENU	SCREEN	MESSAGES	HELP	ENTER
			0	

- 1. Select Main Menu from the On-Screen Selection bar displayed along the bottom of the screen by pressing the button immediately below.
- 2. Rotate the thumbwheel to highlight **Setup** then depress the thumbwheel to select.

Performed By:	Date:
Verified By:	Date:
#### 6.2.2 System Security Verification (Continued)

- 3. Enter "Eng" as User Name by moving thumbwheel to desired letter and depressing thumbwheel.
- 4. Select ACCEPT Button (located on the on screen selection bar at the bottom of the screen).
- 5. Enter "PASS" as password.
- 6. Select ACCEPT Button (located on the on screen selection bar at the bottom of the screen).
- 7. Select Setup.
- 8. Select Edit.
- 9. Select General.
- 10. Select Password.
- 11. Select Protect Menu.
- 12. Select Setup then select Technician.
- 13. Select Record then select Technician.
- 14. Select Layout then select Technician.
- 15. Select Screen then select Technician.
- 16. Select Totals then select Technician.
- 17. Select Counters then select Technician.
- 18. Select Context Menu then select Technician.
- 19. Click Back.
- 20. Select **Options** from the Password Menu.
- 21. Select No reuse for and enter 4 times using the thumbwheel.
- 22. Select ACCEPT Button.
- 23. Select Expires in and enter 1 days using the thumbwheel.
- 24. Select ACCEPT Button.
- 25. Select Timeout in and enter 10 minutes using the thumbwheel.
- 26. Select ACCEPT Button.
- 27. Select Password from Password Menu.
- 28. Document the number of users allowed \_\_\_\_\_. Expected value: 20
- 29. Test Results: Pass/Fail:

Performed By:	Date:	
Verified By:	Date:	



Page of

#### 6.2.2 System Security Verification (Continued)

- 30. Scroll down to 1<sup>st</sup> No User.
- 31. Click Enter.
- 32. Scroll down to Create User. Enter



- 33. Using the Text Entry screen, enter the following information: User Name: Honey01, Level: Supervisor
- 34. Click Accept.
- 35. Enter time and date of User Name Honey01 creation:
- 36. Return to General Menu.
- 37. Select User Honey01
- 38. Expected Results: User will be asked to enter new password.
- 39. Enter TEMP01 for password. Reenter TEMP01 when asked to re-enter.
- 40. Reenter Password Menu as Eng. Enter Password "PASS"
- 41. Repeat Steps 30 34 entering information User Name: Honey02, Level: Technician, Password: TEMP01 for 2<sup>nd</sup> available user.
- 42. Verify that system does allow the use of TEMP01 for password. (Duplicate Passwords are permitted).
- 43. Test Results: Pass/Fail:
- 44. Enter TEMP02 as Password.
- 45. Return to Main Menu
- 46. Select Finish and Apply.
- 47. Select Setup
- 48. Select Honey02, enter password TEMP02.
- 49. Verify "Password entry error" displayed and no entry to Setup for user level technician was given.
- 50. Test Results: Pass/Fail: \_\_\_\_\_\_
  Performed By: \_\_\_\_\_

Date:

Date:

Ve	rifie	d B	v.
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6.2.2	System Security Verification (Continued)					
51.	Verify more than 1 day has passed since time documented in Step 35.					
52.	Enter system as Honey01.					
53.	Verify message appears: Password has expired. You must enter another					
54.	Test Results: Pass/Fail:					
55.	Verify user can change their passwords and cannot reuse a password for 4 times. Enter Menu Select Honey01. Select Change Password.					
56.	Enter current password (Temp01) then enter Temp01 as password. Follow on screen instructions and verify password by reentering Temp01.					
57.	Verify error message displayed.					
58.	Test Results (for password reuse 1): Pass/Fail:					
59.	Repeat steps 55 – 57 three additional times.					
60.	Test Results (for password reuse 2): Pass/Fail:					
61.	Test Results (for password reuse 3): Pass/Fail:					
62.	Test Results (for password reuse 4): Pass/Fail:					
63.	Enter TEMP03 as Password.					
64.	Return to Main Menu					
65.	Log in as Honey01. Document time and date of login:					
66.	Wait 10 minutes from time documented in Step 65.					
67.	Attempt to enter the Menu. Verify no access is given and user is required to login.					
68.	Test Results: Pass/Fail:					
69.	Log in as user Honey01 with password TEMP03.					
70.	Verify access is granted.					
71.	Test Results: Pass/Fail:					
72.	Enter Setup Menu as Eng, Password PASS.					
73.	Return to Password Menu.					
74.	Select Reset Password.					
75.	Select Password and verify no users are defined other than default Eng.					
76.	Test Results: Pass/Fail:					
Comr	nents:					
Perfo	rmed By: Date:					

	Date
Varified Dw	Data
	Date

## 6.2.3 System Calibration

To ensure that all instruments requiring calibrations have been placed into a calibration program.					
All instruments requiring calibration hav program and there is a current certificati	ve been placed into a calibration on in effect.				
1. List the calibration information for the recorder. Any input channels calibrated individually (no 'F' indicated when thumbwheel is used to select Inputs, then Calibrate) must be listed separately.					
2. Attach a copy of the calibration documentation.	certificates in the support				
Certification Number and Expiration Date	Test Results Pass Fail/ Initial Date				
Comments:					
	To ensure that all instruments requiring a calibration program. All instruments requiring calibration hav program and there is a current certification thannels calibrated individually thumbwheel is used to select Im separately. 2. Attach a copy of the calibration documentation. Certification Number and Expiration Date				

Performed By:

Verified By:

Date:

Date:

## 6.2.4 Power Failure and Emergency Cut Off Verification

Purpose	Document that the Uninterruptible Power Supply (UPS) back-up system provides continuous power to the Honeywell MiniTrend V5 recorder and that emergency disconnect switch is properly labeled.					
Acceptance Criteria	The Honeyw failure and the disconnect set	The Honeywell MiniTrend V5 recorder remains operational with a power failure and that power may be disconnected by means of emergency disconnect switch.				
Procedure	1. Rem pow	nove the power cord connecting the UPS er failure.	S to the outlet to simulate			
	2. Sugg	gested period of time is 5 minutes. Iden er disconnect: Period of time:	tify actual time period of			
	3. Doc	ument the time that power was disconne	ected.			
	4. Time	e of main power disconnect:	_			
	5. Wait	t for time period identified in Step 2.				
	6. Reco	onnect main power to the recorder.				
	7. Time	e of main power reconnect:				
	8. Veri Step	Verify that screen remains active for full time period identified in Step 2.				
	9. Veri swite	fy disconnect switch is operational by a ch.	ectivating disconnect			
	10. Expe not i	ect recorder to turn off. UPS should be nterfere with emergency disconnect.	connected so that is does			
Expected Resul	lts	Actual Results	Test Results Pass Fail/ Initial Date			
Power is not interrupted wh	nen Power					
Cord is removed.	Emergency					
Disconnect switch is activated.						
Comments:						

Performed By:

Date:

Date: \_\_\_\_\_

Verified By:

## 6.2.5 Input/Output Verification

Purpose	To ensure that input and output configuration performs in accordance to user configuration and manufacturers specification.				
Acceptance Criteria	All installed I/O performs in accordance to user configuration.				
Procedure	1. Refer to 6.1.5 for pen specification.				
	2. Complete I/O Challenge Table in its entirety.				
	3. Place N/A, initial and date in table for all non-configured I/O.				
	4. Source refers to Analog Input Range and Measure refers to pen engineering range.				
	5. Perform a one-point challenge for all configured I/O and document results. Use the identified acceptable source and measure from 6.1.5 configuration.				

Performed By:

Date:						

Date: \_\_\_\_\_

Verified By: \_\_\_\_\_

6.25 I/O Challenge Table							
Category/Name Enter Input Name	Source	Measure	Pass /Fail Initial / Date	Туре	Off State	On State	Pass /Fail Initial / Date
A1				Channel 1			
A2				Channel 2			
A3				Channel 3			
A4				Channel 4			
A5				Channel 5			
A6				Channel 6			
A7				Channel 7			
A8				Channel 8			
A9				Channel 9			
A10				Channel 10			
A11				Channel 11			
A12				Channel 12			
A13				Channel 13			
A14				Channel 14			
A15				Channel 15			
A16				Channel 16			

Performed By: \_\_\_\_\_

Date:

Verified By: \_\_\_\_\_

## 6.2.6 Custom Verification

Purpose	To ensure all aspects of custom configuration has been challenged and works according to user requirements.				
Acceptance Criteria	All alarms, custom screens, graphs, events and custom Excel graphs/reports have been identified and verified to work in accordance to user specifications.				
Procedure	<ol> <li>Complete the tables below in their entirety.</li> <li>Place N/A with initials and date for any non-applicable tests or table blocks.</li> <li>Alarms: Identify each pen configured for an alarm.</li> <li>Document alarm configuration and test performed to challenge each alarm.</li> </ol>				

Pen Identification	Alarm Configuration	Test Performed	Test Results Pass/Fail Initial Date

Performed By:

Date:

Verified By: \_\_\_\_\_

## 6.2.6 Custom Verification (Continued)

Pen Identification	Alarm Configuration	Test Performed	Test Results Pass/Fail Initial Date

Maths: Identify each pen configured for Math. Document math expression and test performed to challenge math expression. Use additional sheets if applicable				
Pen Identification	Math Expression	Test Performed	Test Results Pass/Fail Initial Date	

Performed By: \_\_\_\_\_

Date:

Verified By:

## 6.2.6 Custom Verification (Continued)

Pen Identification	Math Expression	Test Performed	Test Results Pass/Fail Initial Date

#### Dual Redundancy of data storage Indicate if Dual Redundancy of data storage is configured: Yes No

If Yes complete Table below. If No place single line through table, indicate N/A, place initials and date on line.

Successfully transfer data to recordable medium. Place one at a time graph on TrendViewer. Print				
graph from each medium. Verify data is identical on each graph.				
Pen	Graph Value (Floppy)	Graph Value (PCMCIA)	Test Results: Pass/Fail Initial/Date	

Performed By:

Date:

Verified By: \_\_\_\_\_

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## 6.2.6 Custom Verification (Continued)

Pen	Graph Value (Floppy)	Graph Value (PCMCIA)	Test Results: Pass/Fail Initial/Date

Performed By:

Date:				

Verified By: \_\_\_\_\_

Date:

## 6.2.6 Custom Verification (Continued)

Totals: Identify each pen configured for totals.

Document expression and test performed to challenge expression.

Pen Identification	Expression	Test Performed	Test Results Pass/Fail Initial Date

Performed By:

Verified By:

## 6.2.6 Custom Verification (Continued)

- 1. Attach a Screen Shot for each Custom Screen designed (Print from Screen Designer) and annotate configuration. Label each Custom Screen Attachment 6.2.6-Custom Screen (1-XX)
- 2. Sign and initial each screen. For each attachment view custom screen on recorder, compare custom screen to printed attachment from Screen Designer and verify displayed screen matches user specification.

Screen Name	Test Results Pass/Fail Initial Date	Comments

Performed By:

Verified By: \_\_\_\_\_

### Page \_\_\_\_\_Of \_\_\_\_Protocol Attachment Document # 103

## 6.2.6 Custom Verification (Continued)

Graphs			
1. Identify each graph created on TrendManager Pro.			
2. Challenge data displayed on each graph is as configured and accurate.			
3. Use additional sheets if necessary.			
Graph Name	Test Result Pass/Fail Initial/Date		

Performed By: \_\_\_\_\_

Verified By:

## 6.2.6 Custom Verification (Continued)

Category					
Excel Graphs/Worksheets	Excel Graphs/Worksheets				
1. Identify each Excel Worksheet /Graph	a created on TrendManager Pro.				
2. Challenge data displayed on each graph is as configured and accurate.					
3. Use additional sheets if necessary and challenge data is as configured.					
Excel Name Test Result Pass/Fail Initial/Date					

Performed By:

Date:	
-------	--

Verified By: \_\_\_\_\_

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## 6.2.6 Custom Verification (Continued)

Events			
1. Identify each configured event and verify event triggers as expected.			
2. Manually for	orce each event cause	e and document even	t effect occurred.
3. Use additio	nal sheets if applicab	ole.	
Event Name	Cause	Effect	Test Result Pass/Fail Initial/Date

Performed By: \_\_\_\_\_

Verified By: \_\_\_\_\_

#### 6.2.7 21 CFR § 11 Compliance

Purpose	To ensure system complies with regulatory requirements in regards to electronic records.	
Acceptance Criteria	System complies with regulatory requirement in regards to electronic records.	
Procedure	<ol> <li>Complete Table below.</li> <li>Excerpts of 21 CFR § 11 are included for clarity.</li> </ol>	

#### 21 CFR § 11

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.

1. Save a data sample to diskette or PCMCIA card. Start TrendViewer or applicable software and generate graph detailing saved data.

Expected results: Data is generated in a readable form suitable for inspection, review and copying.

Test Results: Pass/ Fail Initial / Date

11.10(c) Protection of records to enable their accurate and ready retrieval throughout the records retention period.

- 1. Identify SOP which details data retrieval and retention.
- 2. Verify SOP provides necessary protection of data through retention period, including backups, fire proof storage, etc.

Test Results: Pass/ Fail Initial / Date

11.10(d) Limiting system access to authorized individuals

- 1. Identify SOP which details system security.
- 2. Verify password setup enabled\_\_\_\_\_

Access previously challenged in OQ section 6.2.2.

Test Results: Pass/ Fail Initial / Date \_\_\_\_\_

Performed By:	Dat	e:
Verified By:	Dat	e:

### 6.2.7 21 CFR § 11 Compliance (Continued)

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

1. Verify that events have been created for minimally the following Causes:

Start and Stop of Logging Setup Changes Recorder Power up Disk or PC Card Full Disk or PC Card Removed Test Results: Pass/Fail Initial/Date

2. Review event list created in 6.2.6 – Events. Verify event list details date and time for each event. Test Results: Pass/Fail Initial/Date \_\_\_\_\_\_

11.10(g) Use of authority checks to ensure only authorized individuals can use the system, electronically sign a record, secure, time-stamped audit trails for operator actions on the records.

11.10(i) Determination that persons who develop, maintain, or use electronic records and signatures have the education, training and experience to perform their assigned tasks.

- 1. Identify SOP which details training.
- 2. Verify SOP provides necessary direction relating to electronic records and signatures.

Test Results: Pass/ Fail Initial / Date

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.
- 1. Identify SOP which details documentation control.

Performed By:

2. Verify SOP provides necessary detail in regards to electronic records and signatures.

Test Results: Pass/ Fail Initial / Date \_\_\_\_\_

Date:		

Verified By:

Purpose	To ensure the support software performs in accordance to manufacturers specifications.
Acceptance Criteria	Support software performs in accordance to manufacturers specifications.
Procedure	Complete the tables below in their entirety.

TrendViewer			
Step	<b>Expected Result</b>	Actual Result	Performed by Initial /
			Date
TrendViewer previously	Graph Displayed		
tested in 6.1.14.			
Document if			
TrendViewer displayed			
data.			

- 1. TrendManager Pro
- 2. Challenge Import / Export Data Configuration.
- 3. Save Recorder configuration to disk and start TrendManager Pro.
- 4. Document name of recorder from export:
- 5. Select Import, Setup and verify directory reflects where diskette is stored. Select YES
- Expected results: Recorder name identified in Step 2 is now listed in Recorder Panel. Test Result Pass/Fail
- 7. Click on Recorder Name and Select Open.
- 8. Select 1<sup>st</sup> instance of recorder configuration and Select OK.
- 9. Modify Recorder Name to OQ Challenge
- 10. Save changes by selecting OK then YES Overwrite.
- 11. Reopen Recorder Configuration and select Transfer Icon.
  - 12. Verify Directory reflects actual drive and select Yes.

Performed By:

Date:

Verified By:	
--------------	--

Date:

- 13. Reload configuration on recorder.
- 14. Verify that recorder name is now reflected as OQ Challenge.

Test Result Pass/Fail

15. Return recorder name to original value.

16. Challenge Default Report.

17. Select recorder identified in Step 2 from Recorder Panel by double clicking.

18. Select Print Icon

19. Select 1<sup>st</sup> Instance OK

20. TrendManager Pro (Continued)

21. General Tab Select Print General Setting and Pen Hardware Settings

22. Select Pens Tab.

23. Add Pen 1 through Pen 4 if configured else only configured pens. Document # of Pens if not 4.

24. Click Analogues

25. Add Analog 1 through Analog 4 if configured else only configured analogs. Document # if not 4. \_\_\_\_\_

26. Select Print

27. Select desired printer and Landscape

28. Label each sheet of report 6.2.8 Print

29. Expected results: Report detailing Pen Configuration and Analog configuration will print for each of the selected Pens and Analogs

30. Test Result Pass/Fail \_\_\_\_\_.

31. Challenge Default Report.

Performed By:

Date: \_\_\_\_\_

Verified By:

Date:

32. Import data from Recorder
33. Default Graph is displayed on screen.
34. Select View Data As Icon
35. Select Print Icon. Verify correct printer selected and label 6.2.8 Data View.
36. Click on X to close Window.
37. Select Spreadsheet Export Icon
Export Data to Spreadsheet       Image: Comma Separated Variable (CSV) format.         File names will be in the format of Prefix, RecorderName_PenName.csv where the user is asked for the prefix.       Export Data selected for export is from:         The data exported will be an overview of the actual data to reduce the length of the document.       Image: Comma Separated Variable (CSV) format.         Data selected for export is from:       Triday, July 20, 2001 10:58:20 AM:000° To "Friday, July 20, 2001 2:10:50 PM:000".         Recorder = FQ01 MiniTrend · ID = 0001 · Serial Number = 447860, Pen = MIT09 · Run 1 MIT · Units = "C       Image: Comma Time/Date Format         Image: Comma Time data exported will be an overview of the actual data to reduce the length of the document.       Image: Comma Time/Date Format         Verview of Data       Image: Comma Time/Date Format       Image: Comma Time/Date Format         Time/Date Format       Image: Comma Time data exported will be an overview of the actual data to reduce the length of the document.       Image: Comma Time/Date Format         Image: Comma Time data exported will be an overview of the actual data to reduce the length of the document.       Image: Comma Time/Date Format         Image: Comma Time data exported will be an overview of the actual data to reduce the length of the document.       Image: Comma Time/Date Format         Image: Comma Time data exported will be an overview of Data exported will be an overvie
Image: Second condition     Image: Second condition       38. Above figure appears select Send to Excel
39. Click Export Icon

Performed By:	Date:
Verified By:	Date:

40. Enter destination folder and file name		
Save in: My Documents		
bbunt_2000		
C Download		
My Pictures		
File name: Export		
Save as type: CSV time format (*.csv)		
41. Document selected Folder and File Name:		
42. Expected Results: Excel opens displaying graph data.		
Test Results Pass/Fail:		
43. Format Excel data so that all data is visible.		
44. Print Excel Data and label 6.2.8 Export		
45. Select Done button on TrendManager Pro.		
46. Select Printer Icon – Standard Print		
47. Select Applicable Printer. <b>OK</b>		
48. Label 6.2.8 Standard Print.		
49. Select Printer Icon – Legend Print		
50. Select Applicable Printer. <b>OK</b>		
51. Label 6.2.8 Legend Print.		
52. Compare all data including date and time and number format of Excel data to date and time of 6.2.8 .Data View.		
53. Expected Results: Data is for the same period and format on both Excel and internal reports.		
Test Results Pass/Fail:		
Performed By: Date:		
Verified By: Date:		

Challenge Email Export (Perform only if Mail Service	available on test computer)
54. Select Spreadsheet Export Icon	×
Export Data to Spreadsneet Export Data to Spreadsneet Export per readings in Comma Separated Variable (CSV) format. File names will be in the format of Prefix_RecorderName_PenName.csv where the user is asked for the prefix. Time/Data in normal format. The data exported will be an overview of the actual data to reduce the length of the document. Data selected for export is from: Friday. July 20, 2001 10:58:20 AM:000' To 'Friday, July 20, 2001 2:10:50 PM:000'. Recorder = FQ01 MiniTrend · ID = 0001 · Serial Number = 447860, Pen = MIT09 · Run 1 MIT · Units = "C	Export data Per Readings Totaliser Readings Overview of Data Local Format Lotus 1-2-3. Auto File Name Format Traditional DOS Cung Filenames Some networks require file names no longer than 8 characters. Click Traditional for these otherwise use longer easier to recognise names. Send to Excel Email
	Done
Above figure appears select Send to Email	
55. Click Export Icon	
56. Enter desired destination folder and name: Document	
57. Select Save	
58. Mail Selector Figure appears. Note Expect your sp Choose Profile Profile Name: MS Exchange Settings  New OK Cancel Help Options >>	ecific mail service.
59. Select OK	
60. Expected Results: Mail Service Opens with the data in a Test Results Pass/Fail:	in attachment as defined in Step 46.
Performed By:	Date:
Verified By:	Date:

Graphical devices, called *Widgets*, are positioned on to a blank template representing the recorder's screen. The widgets are made up from individual objects which can be modified to suit the users requirements. Each widget displays data in different formats e.g. Chart, Bargraph, or Digital readouts. These can be used in conjunction with Bitmaps to create an exclusive screen design.

The Widgets are:-

DPM - Digital Panel Meter
Bar - Bargraph with Embedded DPM widget
Chart - Traces displayed on a graph
Bitmap - Bitmap images load as a widget
Events List - Lists activity on the recorder
Status Bar - Displays system information

Perform this challenge if no custom screens have been created or all of the Widgets have not been utilized on custom screens. Individual testing of custom screen was completed in 6.2.6

Performed By:	Date:
Verified By:	Date:

Widgets will appear in the recorder pen colour order.

Extra text can be added at any time. See "User Defined Text" on page 36.

To select the whole widget hold down the shift key whilst selecting the widget.

Pressing delete, with any part of a widget selected, will delete the whole widget.

Right click on the mouse button to access copy, cut and paste options.

Widgets can be resized when objects are toggled off/on in the Objects tab.

Set the data source for a widget by selecting the Set Source icon.

Use the Go icon to animate the widgets on or off the template.

Use the directional arrows on the keyboard to help position widget objects.

Challe	lenge Widgets.	
1.	Start Screen Designer software	
2.	A blank template is displayed.	
3.	. Click on Expert Mode Icon.	
4.	Click on DPM Widget Icon located on left side of screen	
5.	DPM Widget appears on template. Place upper left corner of screen.	
6.	Document Color of Pen 3	
7.	Select Set Source Icon	
8.	. Enter Pen 3 in Set Source Window enter valid Zero and Span for Pen.	
9.	Expected Results is that Widget changes from default color of Pen 1 to Pen 3 co Step 5.	olor identified in
10.	0. Test Results Pass/Fail:	
11.	1. Select Add Text Icon	
Perfo	Formed By:    Date:	
Verif	ified By: Date:	

Date: \_\_\_\_\_

## 6.2.8 Support Software, TrendViewer, TrendManager Pro and Screen Designer (Cont)

12. Edit User Definable Text Window appears. Select Add.
13. Enter Text Challenge.
14. Select whole DPm widget and go to the objects tab.
15. Select Label 3 and turn off. Select Custom Text for label.
<ol> <li>Expected results: Label 3 displaying Text Challenge is displayed on screen Test Results Pass/Fail:</li> </ol>
17. Toggle On/Off Alarm Markers. Select whole widget go to the objects tab.
18. Toggle Alarm Marker 1 off. Expected results Up Arrow is no longer visible. Test Result Pass/Fail:
19. Toggle Alarm Marker 2 off Expected results Down Arrow is no longer visible. Test Result Pass/Fail:
20. Add Bar Widget by clicking on Bar Widget Icon.
21. Place below DPM Widget.
22. Select Bar Object. Red Handles should appear.
23. Select Bar General Level Cap toggle On. Select Cyan Color.
24. Expected results single line appears at maximum current value. Test Result Pass/Fail:
25. Select Bar Type from Bar General. Select Down.for Bar type
<ul><li>26. Expected results level display (color indication) will be displayed in reverse order.</li><li>27. Test Result Pass/Fail:</li></ul>
28. Select Set Source Icon and enter Pen 2.
29. Select Bar Object. Select Based for Bar type
30. Change Base Point to 35.
Performed By: Date:

Verified By: \_\_\_\_\_

\_\_\_\_\_

Date:

Date:

#### 6.2.8 Support Software, TrendViewer, TrendManager Pro and Screen Designer (Cont)

31. Expected results are bar only displays from 35 to 50%.

Test Result Pass/Fail: \_\_\_\_\_

- 32. Select Scale General Tab. More Tab Toggle off Baseline.
- 33. Expected results are graduation lines remain but base line is no longer displayed. Test Result Pass/Fail: \_\_\_\_\_
- 34. Select Chart Wizard Icon. Place Below Bar Widget.
- 35. Select Set Source Icon and click add to enter Pen 1.
- 36. Select Chart Object and select Traces Tab. Toggle Trace 1 visible to No.
- 37. Expected results are trace is no longer displayed on Template. Test Result Pass/Fail: \_\_\_\_\_
- 38. Return Trace 1 back to visible = Yes.

39. Click on Pointer Object.

- 40. From Pointers General Tab select Pointer size. Select Small.
- 41. Expected result is that pointer changes from large to small..

Test Result Pass/Fail: \_\_\_\_\_

- 42. Scale General More Tab.
- 43. Toggle off and on the following: Expected results:
- 44. Baseline switches on/off the main scale line Test Result Pass/Fail:
- 45. Major Grads toggles on / off the major graduations. Test Result Pass/Fail:
- 46. Minor Grads toggles on/off the minor graduations.

Test Result Pass/Fail:

Performed By:		
Verified By:		

47. Limit font change to medium. Changes the font size for the two labels at either end of the scale. Test Result Pass/Fail:
48. Set Automatic to Off Decimal places enter 3. Expect 3 decimal places to be displayed. Test Result Pass/Fail:
49. Leave settings to: Baseline – Off, Major Grads- On, Limit font small and decimal places 3.
50. Select Add New Template Icon.
51. Select New Events List Widget Position at top of screen.
52. Select New Status Bar Widget Position below Events List
53. Leave default settings on.
54. Create two additional templates.
55. Modify third template by placing new DPM Widget and setting to Pen 1.
56. Modify fourth template by placing a new Chart Widget and setting to Pen 2.
57. Display four templates in Tile Mode. Go to Window and select tile.
58. Verify four templates may be displayed at one time in Tile Mode with MiniTrend screen size. Test Result Pass/Fail:
59. Prepare 1 <sup>st</sup> Layout for transfer. Set the source of the data.
60. Set recorders screen ready for transfer to recorder
61. Verify and Save the Layout in file frompc.tv as file type lyt on to floppy disk.

Performed By:	Date:
Verified By:	Date:

62. Insert disk in recorder and Load Layout.

63. Verify Screen Designed in layout one is now displayed on recorder.

Test Result Pass/Fail:

Performed By:	Date:
Verified By:	Date:

## 6.2.9 Validation Test Equipment and Calibration

List the validation equipment used in the execution of this protocol in the table below. Indicate the equipment manufacturer, model number, serial number, and calibration date.

Equipment Description	Manufacturer	Model Number	Serial Number	Date Calibrated	Due Date for Calibration

Comments:

Performed By:	Date:
Verified By:	Date:

## **Protocol Completion**

All items in this protocol were reviewed and found to be acceptable. All variations or discrepancies were satisfactorily resolved.

<b>Review Signatures</b>		Date
	-	
	_	
	_	

Performed By:	Date:
Verified By:	Date: