PR10, PR20 & PR30 Paperless Recorder

AMS2750E Guidelines

**The PR Series paperless recorders
along with end users Standard Operating Procedures (SOP)
can meet the Guidelines specific to Monitoring and Recording Instruments for
Temperature Accuracy and Electronic Records**

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1   Overview

AMS2750E is a Pyrometry (temperature-driven) specification that employs procedures, timelines, calibration data, record archiving, SAT (System Accuracy Testing), TUS (Temperature Survey Surveys) and thermocouple guidelines and applications

This document provides a description of how the PR along with an end user's validated Standard Operating Procedures (SOPs) can meet the AMS2750E guidelines for "Recorders" specific to accuracy, electronic records, security and the specific SAT.

2   PR & Historical Viewer

2.1   Paperless Recorder PR: PR10, PR20 &PR30

PR is a paperless recorder with a maximum of 48 channels directly connected universal inputs of measurements.

2.2   Historical Viewer

Historical viewer is a PC based software for playback the measurement data in both trend graph and digital format. Log information (Alarm log, Event log, …) can be displayed as well. All necessary information can be printed out using standard printers. Data conversion to major spreadsheet formats and PDF also supported.

3   Operation Security

AMS2750E requires that access to systems that are used to create, modify, maintain, or retrieve electronic records must be limited to authorized individuals. Additionally, authority checks are required to assure that authorized individuals accessing the systems are able to perform only tasks for which they have the appropriate level of access and for which they have been properly trained.

3.1   Configuration Security in PR

PR has a key-lock function and password protection for configuration parameters.

3.2   Login Security in PR

PR can be configured to utilize a combination of user name, and password to limit system access to authorized users. Each user name must be unique. Each user permissions can be further defined for various functions. PR allows the configuration of a maximum of 30 users with 9 different access levels. Limiting system access to authorized users and controlling individual levels of access provide effective security for the use of the instrument.

3.3   Access Security in PR

PR has a physical locking system on its front door, which prevents unauthorized access to the external media and to the pause switch.

4   Data Security

AMS2750E requires that records are protected so that they can be retrieved readily and accurately throughout any required retention period. This requirement applies not only to records at their time of creation but also to archived electronic records for the duration of their storage period.

4.1   Date File Management in PR

PR data files are stored in a proprietary encrypted binary format and as such cannot be modified once they have been created. Acquired data, such as temperature values, are also stored in a proprietary binary format and cannot be changed once they have been stored.

PR maintains records of all alarms, alarm acknowledgements, error messages in the same binary files. These files cannot be changed by users or administrators. An error message will appear the next time anyone attempts to access the data notifying the user that the file is damaged and cannot be viewed.

Historical Viewer software will display and print data in human-readable form. The files can be easily copied for backups, archiving, inspection, and review. The software will not allow a user to overwrite records or automatically overwrite records.

5   Batch

AMS2750E requires that lots (batches) and sub-lots (batch no) of identical parts are to be identified to preclude their mixing and to ensure lot integrity.

5.1   Batch in PR

PR has a Batch function. Once the batch mode is enabled the users can input batch name and a lot number for each batch record along with batch comments. The batch name together with the lot number can be used as the file name of the data file. PR can be operated in either a Batch or Continuous mode for data collection.

The Historical Viewer software shows batch header information together with the measurement data record

6   AMS2750E Compliance Table

AMS2750E Requirement	PR Compliance
Test Instruments, Controlling, Monitoring or Recording Instruments	
3.2.2 & 3.2.3.1 Minimum Readability At least one recording and/or controlling instrument for each zone to have minimum readability of 1°F or 1°C.	The PR recorder is configurable to display and log temperature data in 1°F or 1°C or 0.1°F or 0.1°C resolution.
3.2.3.2 Recommended Installation Installation shall conform to the manufacturer's recommendations.	The PR user manual provides information on proper installation
3.2.3.3 Sensor Signals Instruments shall receive an unmodified signal from sensors except for A/ D and D/A conversions, or a digitally-processed, error-checked equivalent representation of a directly measured value.	PR accepts all T/C sensor inputs as listed in Table 2. All signals are digitally processed. Please refer to the user manual for measurement accuracy.

AMS2750E Requirement	PR Compliance
3.2.4 Offsets If offsets are used, a documented procedure shall exist, describing when and how to perform offsets.	The PR provides an option to introduce offsets for each input in the configuration in 0.01°increments (°F or °C) as documented in the user manual. The PR provides an option of 64 points transformation table through Math channel for calibration correction.

Instrument Calibration

AMS2750E Requirement	PR Compliance
3.2.5.2 Calibration Accuracy and Interval Calibration accuracy and interval requirements for Controlling, Monitoring or Recording Instrument shall be in accordance with Table 3. **Table 3: Digital Instruments Accuracy** ±2°F (±1.1°C) or 0.2% of the maximum survey temperature of the equipment, whichever is greater. **Calibration Interval** Interval is based upon furnace class.	❖ The field calibration option is available and the procedure is described in the user manual. This requires high accuracy input simulation equipment to properly calibrate the instrument. ❖ Calibration Interval is the responsibility of the user.
3.2.5.3 Sensitivity ❖ Sensitivity shall be checked during calibration; see Table 3 footnote 4; ❖ Furnace Class 1 & 2 instruments shall have a minimum sensitivity of 1°C or 1°F while classes 3 through 6 shall have a minimum sensitivity of 3°F (2°C).	Minimum Sensitivity of PR is 0.1°F or 0.1°C.
3.2.5.4 Calibration Calibration of field test instruments shall be performed in accordance with the manufacturer's instructions.	The calibration procedure is explained in the PR user manual
3.2.5.5.4 Calibration with Load Calibration of controlling, monitoring or recording instruments may be performed with a load in the process if ❖ the temperature remains within the processing tolerance ❖ the furnace temperature record is appropriately annotated to indicate that a calibration occurred including time and date.	❖ The PR logs the calibration log in the event log with date and time. ❖ The users can easily annotate in the digital records by using the handwriting function in the PR

AMS2750E Requirement	PR Compliance
3.2.5.5.5 Furnaces used at a single temperature For furnaces used only at a single temperature, the calibration may either be performed per the manufacturer's instructions at the single temperature of use or with a minimum of 3-points; the temperature of use and 2 or more points bracketing the temperature of use.	The field calibration option is available and the procedure is described in the user manual. This requires high accuracy input simulation equipment to properly calibrate the instrument.

Electronic Data Record

AMS2750E Requirement	PR Compliance
3.2.7.1 Electronic Records An "electronic record" is any combination of text, graphics, data, audio, pictorial, or other information representation in digital form that is created, modified, maintained, archived, retrieved, or distributed by a computer system. When using a system (furnace control, recording, monitoring or data acquisition) that creates electronic records, systems purchased after Sept 2006 or any electronic record created after 2015 (3 years after the release of this revision) shall meet the following requirements: ❖ 3.2.7.1.1 ❖ 3.2.7.1.2 ❖ 3.2.7.1.3 ❖ 3.2.7.1.3.1 ❖ 3.2.7.1.4 ❖ 3.2.7.1.5	The PR is suitable to use as defined by clause 3.2.7.1 and the noted subsections shown in below rows of the table.
3.2.7.1.1 Encrypted Electronic Records The system must create electronic records that cannot be altered without detection.	❖ The PR electronic records (data log and event log files) are electronically (digitally) signed by the system when the file is created. The file can't be altered. ❖ When the file is viewed in the PC software "Historical Viewer" the software will prompt the user to digitally sign before closing the file (encrypted signature). ❖ The data files and event log files are stored in a proprietary binary format and cannot be changed once they have been stored. ❖ If the user attempt to change any data by directly accessing the binary data, the file will become useless to the user. An error message will appear the next time anyone attempts to access the data notifying the user that the data has been changed and the file cannot be viewed.

AMS2750E Requirement	PR Compliance
3.2.7.1.2 Electronic Records Playback without alteration The system software and playback utilities shall provide a means of examining and/or compiling the record data, but shall not provide any means for altering the source data.	❖ PR allows for playback in trend-graph format. The Historical viewer software displays and prints data in human-readable form. Such files can be easily copied for backups, archiving, inspection and review. ❖ When viewing a data logfile from PR or PC software "Historical Viewer" there is no manner to alter the source data as the log files are logged in manufacturer's binary format.
3.2.7.1.3 Electronic Records Viewing and Copying (file export) The system shall provide the ability to generate accurate and complete copies of records in both human-readable and electronic form suitable for inspection, review, and copying.	❖ PR allows for record generation in both human-readable form and electronic form for inspection, review, and copying. ❖ The logged data and events can be viewed on the PR History Page and Event Page ❖ The encrypted historical data can be exported to the PC software "Historical Viewer" and analyzed. The data can be viewed only. It can't be altered. ❖ Data may be exported from the recorder via USB, SD Card and Ethernet connections. ❖ When Data files are opened in PC software Historical Viewer they can be printed, exported to excel for inspection and analysis.
3.2.7.1.3.1 Electronic Records Evidence of User Review The system shall be capable of providing evidence the record was reviewed – such as by recording an electronic review, or a method of printing the record for a physical marking indicating review.	❖ **Digital Signature(s)** provide evidence of user reviewing record(s) on PR or PC software Historical Viewer. Additional encrypted digital signatures can be added to any closed data file if the user has appropriate security rights. All signatures are date/time stamped and linked to the data file. ❖ **Printing:** Data Files may be exported by USB, SD Card or Ethernet Connection. Once exported and opened in PC based Historical Viewer Software, the data may be printed, reviewed and physically marked indicating it was reviewed and signed. ❖ **Handwriting:** The PR has the option to add the remarks on the historical file by using the handwriting function. The handwritten remarks on the screen can also be reviewed along with historical data on the PC software Historical Viewer.

AMS2750E Requirement	PR Compliance
3.2.7.1.4 Electronic File Protection & Retention for 5-years The system shall support protection, retention and retrieval of accurate records throughout the record retention period. Ensure that the hardware and or software shall operate throughout the retention period as specified in 3.7. **3.7 Records** **3.7.1 Electronic File Protection & Retention for 5-years** All calibration and test records including sensors, standard cells and instruments, system accuracy tests, and temperature uniformity surveys, including any test or survey failures shall be available for inspection and maintained for not less than 5 years.	❖ Data and other files are saved to internal memory. There is an external memory slot available on the recorder. The SD card or USB disk can be used as external memory on the dedicated slot. The maximum size of the external memory used is 32GB. This can store the data for 5 years. ❖ The data files can be exported to PC by using the PC software Historical Viewer. Once the data is exported to PC, it can be stored for a longer time on the PC hard disk for backup.
3.2.7.1.5 Electronic Records Security/Password Protection The system shall provide methods (i.e. passwords) to limit system access to only individuals whose authorization is documented.	❖ PR can prevent illegal data access by unauthorized users with log-in authentication and/or keylock protection. ❖ There are 30 users with 9 levels of security available for the user to configure different levels of security ❖ The 30 users can be assigned with a unique user name and password ❖ The access for different functions can be assigned with different security levels. The user with the proper security level only accesses the functions. ❖ All the operations on the recorder will be logged in the event log for audit trial. ❖ The Event log files can be analyzed on the Event page or on the PC software Historical Viewer software.

AMS2750E Requirement	PR Compliance
Thermal Processing Equipment	
3.3.1 Instrumentation used to Control, Record or Indicate the desired temperature ❖ Furnace classes are defined in Figure 2 and are based on the furnace class specified or when not specified, furnace class shall meet the temperature uniformity requirements established in the specification for the material being processed. Instrumentation types are defined by the level of instrumentation used by the heat treater to control, record or indicate the desired temperature. ❖ Intervals for system accuracy tests, temperature uniformity surveys, and controlling, monitoring and recording instrument calibrations are based on the combined furnace class and instrumentation type, refer to tables 3, 6, 7, 8, or 9.	❖ When subject to the necessary field calibration, the PR is suitable for use in NADCAP applications in all furnace classes as defined in AMS2750E clause 3.3.1 ❖ The field calibration option is available and the procedure is described in the user manual. This requires high accuracy input simulation equipment to properly calibrate the instrument. ❖ **Offsets:** The PR provides an option to introduce offsets for each input in the configuration in 0.01°increments (°F or °C) as documented in the user manual. ❖ The PR provides an option of 64 points transformation table through Math channel for calibration correction. Offsets: The PR series recorder allows the offset parameters as defined in Table 6
System Accuracy Tests (SATs)	
3.4.5.6 Calibration Limitations Adjustment of the control or recording instrument calibration is permitted with the maximum adjustment limitations of Table 6 or 7. The effect of this adjustment over the entire operating temperature range shall be evaluated. Paragraph 4.2 shall apply.	PR allows entry and display of offset parameters meeting the requirement.

Note:
- ❖ AMS2750E compliance is applicable with input types of Thermocouples J, K, T, E, N, L, U, P, W5 or C, W3, LR, A1, A2, A3, M, and RTD only.

- ❖ Plus 1 version firmware, CFR21 security mode, Field Calibration are required to meet AMS2750E compliance

- ❖ Future Design Controls provides no warranty or representations of any sort regarding the fitness of use or application of its products by the purchaser. Users are responsible for the selection, suitability of the products for their application or use of Future Design Controls products.

- ❖ Further information on the PR Series Paperless Recorders can be found at:
  http://www.futuredesigncontrols.com/PR_Series_Paperless_Recorders.htm