



## PR10, PR20 & PR30 Paperless Recorder AMS2750F 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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## Revision History

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## **1 Overview**

AMS2750F 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 describes how the PR10, PR20 & PR30 along with an end user's validated Standard Operating Procedures (SOPs) can meet the AMS2750F guidelines for "Recorders" specific to accuracy, electronic records, security and the specific SAT.

## **2 PR10, PR20 & PR30 & Historical Viewer**

### **2.1 Paperless Recorder PR: PR10, PR20 & PR30**

PR10, PR20 & PR30 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**

AMS2750F 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 can 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 PR10, PR20 & PR30**

PR10, PR20 & PR30 has a key-lock function and password protection for configuration parameters.

### **3.2 Login Security in PR10, PR20 & PR30**

PR10, PR20 & PR30 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. PR10, PR20 & PR30 allows the configuration of a maximum of 30 users with 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 PR10, PR20 & PR30**

PR10, PR20 & PR30 has a physical locking system on their front door, which prevents unauthorized access to the external media and the pause switch.

## **4 Data Security**

AMS2750F 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 Data File Management in PR10, PR20 & PR30**

PR10, PR20 & PR30 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.

PR10, PR20 & PR30 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**

AMS2750F 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 PR10, PR20 & PR30**

PR10, PR20 & PR30 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. PR10, PR20 & PR30 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 AMS2750F Compliance Table

AMS2750F Requirement	PR10, PR20 & PR30 Compliance
<b>3.2 Instrumentation</b>	
<p><b>3.2.1.3 Calibration Accuracy:</b> Instruments shall be calibrated in accordance with Table 7 and shall be traceable to NIST or other internationally recognized standards organization.</p> <p><b>Table 7: Calibration Accuracy</b> Digital type control, recording, data acquisition instrument have the calibration accuracy of <math>\pm 2.0^{\circ}\text{F}</math> or <math>\pm 1.1^{\circ}\text{C}</math> or 0.2% of temperature reading, whichever is greater.</p> <p>Digital control instruments that only read in whole numbers shall have maximum calibration accuracy of <math>\pm 2^{\circ}\text{F}</math> or <math>\pm 1^{\circ}\text{C}</math> or <math>\pm 0.2\%</math> of the temperature reading rounded inward towards the smaller whole number.</p>	<p>The PR10, PR20 &amp; PR30 recorder is suitable for use as defined by clause 3.2.1.3 subject to the necessary field calibration. The calibration certificate validates the instrument measurement calibration for all supported measurement ranges. AMS2750F requires periodic calibration for the field instruments. There are two types of calibration are available and described in the user manual:</p> <ul style="list-style-type: none"> <li>❖ Input Offset and Gain in the input configuration to meet the required accuracy</li> <li>❖ On-Field Calibration using the Calibration procedure: This requires high accuracy input simulation equipment to properly calibrate to factory standards.</li> <li>❖ Calibration Interval is the responsibility of the user.</li> </ul>
<p><b>3.2.1.4 Display Resolution:</b> Resolution requirements for analog recording instruments shall be following Table 8</p> <p><b>Table 8: Display Resolution</b> Digital instruments shall have readability of <math>0.1^{\circ}\text{F}</math> or <math>0.1^{\circ}\text{C}</math></p> <p><b>3.2.3.2 Display Resolution:</b> Digital recording instruments shall have minimum readability of <math>0.1^{\circ}\text{F}</math> or <math>0.1^{\circ}\text{C}</math> within 2 years after the release of AMS2750F</p>	<p>The PR10, PR20 &amp; PR30 recorder is configurable to display and log temperature data in <math>0.1^{\circ}\text{F}</math> or <math>0.1^{\circ}\text{C}</math> resolution.</p>
<p><b>3.2.3.4 Sensor Signals</b> 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.</p>	<p>The PR10, PR20 &amp; PR30 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.</p>
<p><b>3.2.3.19 Clock Time Synchronization:</b> The timing function for all digital recording instruments and data acquisition systems shall be calibrated annually and shall be accurate to <math>\pm 1</math> min/h. Alternatively, a documented digital synchronization of timing systems to NIST (or international equivalent) via satellite, internet, or telephonic systems periodically (at least monthly) to support a <math>\pm 1</math> min/h accuracy is acceptable.</p>	<p>The PR10, PR20 &amp; PR30 has clock time synchronization function via Internet or PC software</p>

AMS2750F Requirement	PR10, PR20 & PR30 Compliance
<p><b>3.2.4 Electronic Records</b></p> <p><b>3.2.4.1</b> 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.</p> <p><b>3.2.4.2</b> When using a system (control, recording or data acquisition) that creates electronic records the system shall meet the following:  <b>3.2.4.2 -a, b, c, d, e, f, g</b></p>	<p>The PR10, PR20 &amp; PR30 is suitable to use as defined by clause <b>3.2.4</b></p>
<p><b>3.2.4.2-a Encrypted Electronic Records</b>  Create records that cannot be altered without detection.</p>	<ul style="list-style-type: none"> <li>❖ The PR10, PR20 &amp; PR30 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.</li> <li>❖ 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).</li> <li>❖ The data files and event log files are stored in a proprietary binary format and cannot be changed once they have been stored.</li> <li>❖ 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.</li> </ul>
<p><b>3.2.4.2-b Electronic Records Playback without alteration</b>  Provide software and playback utilities as a means of examining and/or compiling the data but shall not allow the user any means for altering the source data.</p>	<ul style="list-style-type: none"> <li>❖ PR10, PR20 &amp; PR30 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.</li> <li>❖ When viewing a data log file from PR10, PR20 &amp; PR30 or PC software “Historical Viewer” there is no manner to alter the source data as the log files are logged in the manufacturer's binary format.</li> </ul>

AMS2750F Requirement	PR10, PR20 & PR30 Compliance
<p><b>3.2.4.2-c Electronic Records Viewing and Copying (file export)</b>            Provide the ability to generate accurate and complete copies of records in both human-readable and electronic form suitable for inspection, review, and duplication.</p>	<ul style="list-style-type: none"> <li>❖ PR10, PR20 &amp; PR30 allows for record generation in both human-readable form and electronic form for inspection, review, and copying.</li> <li>❖ The logged data and events can be viewed on the PR10, PR20 &amp; PR30 History Page and Event Page</li> <li>❖ 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.</li> <li>❖ Data may be exported from the recorder via USB, SD Card and Ethernet connections.</li> <li>❖ When Data files are opened in PC software Historical Viewer they can be printed, duplicated, exported to excel for inspection and analysis.</li> </ul>
<p><b>3.2.4.2-d Electronic Records Evidence of User Review</b>            Be capable of providing evidence the record was reviewed by recording an electronic review, or a method of printing the record for a physical marking verifying review.</p>	<ul style="list-style-type: none"> <li>❖ <b>Digital Signature(s)</b> provide evidence of user reviewing record(s) on PR10, PR20 &amp; PR30 or PC software Historical Viewer. <u>Additional encrypted digital signatures can be added to any closed data file if the user has appropriate security rights.</u> All signatures are date/time stamped and linked to the data file.</li> <li>❖ <b>Printing:</b> 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.</li> <li>❖ <b>Handwriting:</b> The PR10, PR20 &amp; PR30 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.</li> </ul>

AMS2750F Requirement	PR10, PR20 & PR30 Compliance
<p><b><u>3.2.4.2-e Electronic File Protection &amp; Retention</u></b> Support protection, retention, and retrieval of accurate records throughout the record retention period.</p> <p><b><u>3.2.4.2-f System will operate throughout the retention period</u></b> Ensure that the hardware and/or software shall operate throughout the retention period as specified in 3.7.</p> <p><b><u>3.7 Records</u></b> <b><u>3.7.1 Electronic File Protection &amp; Retention for 5-years</u></b> 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.</p>	<ul style="list-style-type: none"> <li>❖ 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.</li> <li>❖ The data files can be exported to the PC by using the PC software Historical Viewer. Once the data is exported to the PC, it can be stored for a longer time on the PC hard disk for backup.</li> </ul>
<p><b><u>3.2.4.2-g Electronic Records Security/Password Protection</u></b> Provide methods of protection, such as a password, to limit system access to only individuals whose authorization is documented.</p>	<ul style="list-style-type: none"> <li>❖ PR10, PR20 &amp; PR30 can prevent illegal data access by unauthorized users with log-in authentication and/or key lock protection.</li> <li>❖ There are 30 users with different levels of security available for the user to configure different levels of security</li> <li>❖ The 30 users can be assigned with a unique user name and password</li> <li>❖ The access for different functions can be assigned with different security levels. The user with the proper security level only accesses the functions.</li> <li>❖ All the operations on the recorder will be logged in the event log for the audit trail.</li> <li>❖ The Event log files can be analyzed on the Event page or the PC software Historical Viewer software.</li> </ul>
<p><b><u>3.2.4.3 Software Revisions effect with Continued Compliance with the Material or Process Specifications (3.2.4.3)</u></b> Evidence shall be provided that software revisions are verified to ensure continued compliance with the material or process specification requirements and once installed have not altered programs, recipes, or other means used to control thermal processing parameters.</p>	<p>The PR10, PR20 &amp; PR30 is suitable for use as defined by clause 3.2.4.3 when a firmware or software revision is installed. The software and firmware revision installed will add functions and/or correct identified deficiency (i.e. bug) but does not affect the core functions. Upon release, a software and firmware release note are available noting the changes.</p>



AMS2750F Requirement	PR10, PR20 & PR30 Compliance
<p><b><u>3.2.6.1 General Instrument Correction and Modification Offset Requirements</u></b></p> <p><b>3.2.6.1.2</b> The maximum cumulative correction offset shall not exceed the uniformity tolerance for the thermal processing equipment or <math>\pm 5.0</math> °F or <math>\pm 2.8</math> °C for refrigeration and quench instruments. (e.g., a class 2 furnace instrument is limited to a maximum correction offset of <math>\pm 10.0</math> °F or <math>\pm 6.0</math> °C).</p> <p><b>3.2.6.1.4</b> Controlling instrument modification offsets for TUS shall not exceed the allowances in Tables 18 or 19. SAT modification offsets are not allowed.</p> <p><b>3.2.6.1.5</b> Control and recording instrument correction offsets for SAT shall not exceed the allowances in Tables 18 or 19. TUS modification offsets are not permitted on recorder channels other than for the channel recording the control sensor temperature.</p>	<p>The PR10, PR20 &amp; PR30 provides an option to introduce offsets for each input in the configuration in 0.1° increments (°F or °C) as documented in the user manual.</p> <p>The PR10, PR20 &amp; PR30 provides an option of 64 points transformation table through the Math channel for calibration correction.</p> <p>When appropriately equipped for the number of temperature sensor inputs, and subject to the necessary field calibration, the PR10, PR20 &amp; PR30 is suitable for use as defined by clause 3.2.6.1 / .2/ .4 / .5</p>
<b>Instrument Calibration</b>	
<p><b><u>3.2.5.2 Calibration Accuracy and Interval</u></b></p> <p>Calibration accuracy and interval requirements for Controlling, Monitoring or Recording Instrument shall be following Table 3.</p> <p><b><u>Table 3: Digital Instruments Accuracy</u></b>  <math>\pm 2^\circ\text{F}</math> (<math>\pm 1.1^\circ\text{C}</math>) or 0.2% of the maximum survey temperature of the equipment, whichever is greater.</p> <p><b><u>Calibration Interval</u></b>  Interval is based upon furnace class.</p>	<ul style="list-style-type: none"> <li>❖ 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.</li> <li>❖ Calibration Interval is the responsibility of the user.</li> </ul>
<p><b><u>3.2.5.3 Sensitivity</u></b></p> <ul style="list-style-type: none"> <li>❖ Sensitivity shall be checked during calibration; see Table 3 footnote 4;</li> <li>❖ Furnace Class 1 &amp; 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).</li> </ul>	<p>The minimum Sensitivity of PR10, PR20 &amp; PR30 is 0.1°F or 0.1°C.</p>
<p><b><u>3.2.5.4 Calibration</u></b></p> <p>Calibration of field test instruments shall be performed following the manufacturer's instructions.</p>	<p>The calibration procedure is explained in the PR10, PR20 &amp; PR30 user manual</p>

AMS2750F Requirement	PR10, PR20 & PR30 Compliance
<p><b>3.2.5.5.4 Calibration with Load</b>            Calibration of controlling, monitoring or recording instruments may be performed with a load in the process if</p> <ul style="list-style-type: none"> <li>❖ the temperature remains within the processing tolerance</li> <li>❖ the furnace temperature record is appropriately annotated to indicate that a calibration occurred including time and date.</li> </ul>	<ul style="list-style-type: none"> <li>❖ The PR10, PR20 &amp; PR30 logs the calibration log in the event log with the date and time.</li> <li>❖ The users can easily annotate in the digital records by using the handwriting function in the PR10, PR20 &amp; PR30</li> </ul>
<p><b>3.2.5.5.5 Furnaces used at a single temperature</b>            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.</p>	<p>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.</p>

<b>Thermal Processing Equipment</b>	
<p><b><u>3.3.1 Instrumentation used to Control, Record or Indicate the desired temperature</u></b></p> <ul style="list-style-type: none"> <li>❖ Furnace classes are defined in Table 11 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.</li> <li>❖ 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 7, 14,15,18 or 19.</li> </ul>	<ul style="list-style-type: none"> <li>❖ When subject to the necessary field calibration, the PR10, PR20 &amp; PR30 is suitable for use in NADCAP applications in all furnace classes as defined in AMS2750F clause 3.3.1</li> <li>❖ 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.</li> <li>❖ <b>Offsets:</b> The PR10, PR20 &amp; PR30 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.</li> <li>❖ The PR10, PR20 &amp; PR30 provides an option of 64 points transformation table through the Math channel for calibration correction.</li> <li>❖ Offsets: The PR10, PR20 &amp; PR30 series recorder allows the offset parameters as defined in Table 6</li> </ul>
<p><b><u>3.3.2 Requirements for furnace instrumentation type classification are shown in Table 12.</u></b></p> <p><b><u>Table 12 - Instrumentation type requirements:</u></b></p> <ul style="list-style-type: none"> <li>❖ The temperature indicated by the control sensor in each control zone shall be recorded by a recording instrument.</li> <li>❖ At least two additional recording sensors in each control zone shall be located to best represent the actual coldest and hottest temperatures in each control zone at any temperature of use based on the results from the most recent temperature uniformity survey.</li> <li>❖ Each control zone shall have over-temperature protection <ul style="list-style-type: none"> <li>▪ The over-temperature protection sensor may also be utilized as the recording sensor representing the hottest location for instrumentation type A or C or as the additional recording sensor for type D+ if in the proper location.</li> </ul> </li> </ul>	<p>When appropriately equipped for the number of temperature sensor inputs, control loops and subject to the necessary field calibration, the PR10, PR20 &amp; PR30 is suitable for use as defined by clause 3.3.2, Table 12.</p>
<p><b><u>3.3.3 Instrumentation Requirements for Refrigeration Equipment and Quench Systems</u></b></p> <p><b><u>3.3.3.2</u></b> -All refrigeration equipment shall be equipped with a temperature recording instrument where time-at-temperature (minimum, maximum, or both) is required.</p> <p><b><u>3.3.3.4</u></b> - Quench systems (immersion or spray) shall be equipped with a sensor that is recorded by a recording instrument.</p>	<p>The PR10, PR20 &amp; PR30 is suitable for use as defined by clause 3.3.3.2 &amp; 3.3.3.4</p>

<b>System Accuracy Tests (SATs)</b>	
<p><b>3.4.4.4 Allowable instrument correction or modification offsets include:</b></p> <p><b>3.4.4.4.1</b> - Internal modification offsets applied to the control and control recording channel instruments solely to correct a skewed TUS distribution. Example: Reading from the control instrument is 1000.0 °F and there is a -3.0 °F modification offset applied electronically to the control instrument. Then +3.0 °F must be added to the 1000.0 °F reading before calculating the difference in 3.4.4.2.</p> <p><b>3.4.4.4.2</b> - A previously documented and specified correction offset to the control or recording instrument to correct an SAT difference. Example: Reading from control instrument is 1352.0 °F and there is a +2.0 °F correction offset for SAT applied manually. Then -2.0 °F must be added to the 1352.0 °F control reading before calculating the difference in 3.4.4.2.</p>	<p>The PR10, PR20 &amp; PR30 allows entry and display of offset parameters meeting the requirement.</p>
<p><b>3.4.5.6 Calibration Limitations</b></p> <p>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.</p>	<p>PR10, PR20 &amp; PR30 allows entry and display of offset parameters meeting the requirement.</p>

**Note:**

- ❖ AMS2750F 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 mandatory to meet AMS2750F 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](http://www.futuredesigncontrols.com/PR_Series_Paperless_Recorders.htm)

**7 Q&A: Electronic Records & Digital Signatures**

**7.1 Q&A: Electronic Records**

Question	Answer
Was an established software development life cycle used?	Yes. The PR10, PR20 & PR30 was designed and validated using a full SDLC “risk” based system to include detailed specifications and validation of all software.
Have code reviews been conducted?	Yes. Code reviews performed throughout validation cycle.
Has System Testing been conducted?	Yes. All system testing complete during DVR (design verification release) validation testing and user field testing.
Has Data Conversion testing been conducted?	Yes. Export data testing completed with signature verification of exported data performed/documented during validation.
Did validation include testing that the system discerns invalid records (i.e., invalid field entries, fields left blank that should contain data, values outside of limits, ASCII characters in numeric-only fields, etc.)?	Yes. Full security validation performed to include user login entry data, field formatting, successful/failed login attempts and audit trail functionality performed/documented during validation.
Can a copy of a single record (in electronic format) be supplied to an inspector?	Yes. Export data testing completed with signature verification of exported data.
Is there test evidence for the audit trail functionality	Yes. Full audit trail functionality testing performed/documented during validation.
Does test evidence exist to demonstrate the operational checks (that is, sequences of events within the system)?	Yes. Operational check testing (include user re-authentication for operational steps) performed/documented during validation.
Does test evidence exist to demonstrate the use of the authority checks (based on role-based permissions)?	Yes. All user and group authentication checks performed/documented during validation.

## 7.2 Q&A: Digital Signatures

Question	Answer
Does test evidence exist for the signature manifestation (full name, date and time)?	Yes. Full digital signature functionality testing performed/documented during validation.
Is the transfer of the signature to another record prevented?	Yes. Digital signatures are applied to a single data file only. Any attempt to alter the digital signature or transfer to another file will result in a failure during signature verification.
Does test evidence exist to document signature actions are captured in the audit trail?	Yes. Full digital signature functionality testing performed/documented during validation.
Does test evidence exist to prove the enforcement of unique username and id?	Yes. Full security validation performed to include user login entry data, field formatting, successful/failed login attempts and audit trail functionality performed/documented during validation.
If, when resetting the account on some systems, a "default" password is assigned, is the user forced to change the password immediately upon log on?	There is no default user/password on PR10, PR20 & PR30 device. Security setup is required by an administrator.
Are system tools used that might allow a system administrator to falsify electronic records and/or electronic signatures?	No. Data files are automatically signed by the system with additional signature for each file that can be added by authorized users. Administrators cannot bypass or alter the automatic system signature added to each data file.
Does the system prevent the deletion or re-assignment of a User ID after it is assigned to an electronic record?	Yes. Electronic records (data files, audit trails) cannot be modified. If they are modified, they will fail the signature verification process.
Does the computerized system include functionality that requires users to periodically change their passwords (password aging)?	Yes. Password ageing functionality testing performed/documented during validation
Does test evidence exist to demonstrate detection of attempts of unauthorized access?	Yes. User login fails written to secure audit trail. Audit trail functionality testing performed/documented during validation
Has testing been conducted to ensure that "inactive" user accounts cannot be activated by unauthorized persons?	Yes. Security/User functionality testing performed/documented during validation