

MCT4 ¼ DIN Controller

AMS2750E Guidelines

**How the ¼ DIN MCT4 along with end users
Standard Operating Procedures (SOPs)
can meet the Guidelines specific to
Control, Monitoring and Recording Instruments
for
Temperature Accuracy and Electronic Records**

Overview

AMS 2750E 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 MCT4 along with an end users validated Standard Operating Procedures (SOPs) can meet the AMS2750E guidelines for “Controllers, Monitors and Recorders” specific to accuracy, electronic records, security and the specific SAT and TUS requirements described below.

AMS2750E Section	Topic	MCT4 Meets the Guidelines
Instruments 3.2.2.3.1	Temperature resolution degrees F or C	√
Instruments 3.2.4	Offsets	√
Instruments 3.2.5.2	Calibration accuracy (+/- 1.1C)	√ and SOP
Instruments 3.2.5.3	Sensitivity (display 1 degree F or C)	√
Instruments 3.2.5.5	Calibration with a load in process	√ and SOP
Instruments 3.2.7.1.1	Electronic Records: Electronic records cannot be altered without detection	√ and SOP
Instruments 3.2.7.1.2	Electronic Records: System software and playback utilities examine data but not allow alteration	√ and SOP
Instruments 3.2.7.1.3	Electronic Records: Copies of records in readable & electronic form to inspect, review, copy	√ and SOP
Instruments 3.2.7.1.3.1	Electronic Records: Evidence of record review	√ and SOP
Instruments 3.2.7.1.4	Electronic Protection: Retention and retrieval of electronic records	√ and SOP
Instruments 3.2.7.1.5	Electronic Records: Security - Password protection	√ and SOP
Thermal Processing Equip 3.3.1	Furnace Classes	√ and SOP
Thermal Processing Equip 3.3.3.1 and .2	Thermal Processing Equipment: Refrigeration and Quench Equipment require Recorder	√ and SOP
SAT 3.4.5.6	SAT System Accuracy Test: Maximum offset entry allowed	√ and SOP
TUS 3.5.21.2	TUS Temperature Uniformity Survey Report: PID settings are Not required as part of report but accessible on site	√

Compliance Legend

√ = Compliant when configured per the provided User Manual

SOP = Must be addressed through customer's standard operating procedures

N/A = Does not apply

Note: 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.

Requirement	MCT4 Capability
<p><u>Instruments</u></p> <p><u>Temperature Display Increments (3.2.2.3.1):</u> At least one recording and/or controlling instrument for each zone to have a minimum readability of 1 degree F or 1 degree C.</p>	<p>The MCT4 is suitable for use as defined by clause 3.2.2.3.1.</p> <ul style="list-style-type: none"> The MCT4 is configurable to display and data log temperatures in 1 degrees C or F.
<p><u>Instruments</u></p> <p><u>Offsets (3.2.4):</u> If the offsets are used, a documented procedure shall exist, describing when and how to enter offsets. The procedure shall address how to account for and reintroduce any intentional offsets.</p> <p>Prior to reintroducing any intentional offsets, any instrument calibration error found shall be taken into account. Adjustments (offsets) greater than those shown in Tables 6 or 7 shall not be used.</p>	<p>The MCT4 is suitable for use as defined by clause 3.2.4.</p> <ul style="list-style-type: none"> The MCT4 provides a means, documented in the user manual, to introduce offsets for each input in 0.1 degree increments (F or C). When in the calibration mode where offsets are entered, the offset values are shown digitally providing a means to document and reintroduce any intentional offset(s). The MCT4 allows offset parameters as defined in Table 6 (maximum permitted adjustment (offset)).
<p><u>Instruments</u></p> <p><u>Instrument Calibration.</u></p> <p><u>Calibration Accuracy and Interval (3.2.5.2)</u> Calibration accuracy and interval requirements for Controlling, Monitoring or Recording Instrument shall be in accordance with Table 3.</p> <p>Table 3:</p> <ul style="list-style-type: none"> Digital Instruments Accuracy: $\pm 2F$ ($\pm 1.1C$) or 0.2% of the maximum survey temperature of the equipment, whichever is greater. Calibration Interval: Interval is based upon furnace class. 	<p>When subject to the necessary field calibration, the MCT4 is suitable for use as defined by clause 3.2.5.2</p> <ul style="list-style-type: none"> Two types of calibration are available and described in the user manual: <ul style="list-style-type: none"> Calibration Offsets (high & low) Manual Calibration using the Factory Calibration procedure: This requires high accuracy input simulation equipment to properly calibrate to factory standards. Calibration Interval is the responsibility of the user.
<p><u>Instruments</u></p> <p><u>Instrument Calibration.</u></p> <p><u>Sensitivity of 1 degree C or F. (3.2.5.3):</u> Sensitivity checked during calibration; see Table 3 footnote 4; Furnace Class 1 & 2 instruments shall have a minimum sensitivity of 1 degree F & C while classes 3 through 6 shall have minimum sensitivity of 3F (2C).</p>	<p>The MCT4 is suitable for use as defined by clause 3.2.5.3.</p> <ul style="list-style-type: none"> Minimum Sensitivity is greater than 1F or 1C.

Requirement	MCT4 Capability
<p><u>Instruments</u> <u>Calibration of Controlling, Monitoring and Recording Instruments.</u></p> <p><u>Calibration with Load</u> (3.2.5.5.4): Calibration of controlling, monitoring or recording instruments may be performed with a load in process if</p> <ul style="list-style-type: none"> • the temperature remains within the processing tolerance • the furnace temperature record is appropriately annotated to indicate that a calibration occurred including time and date. 	<p>The MCT4 is suitable for use as defined by clause 3.2.5.5.4 if the “furnace temperature record” is the active Data Log file</p> <ul style="list-style-type: none"> • The MCT4 allows adding annotations of up to 16-characters anytime data logging is active. <ul style="list-style-type: none"> ○ There is no limit to the number of annotations that may be added to an active data file. ○ When an annotation is saved the system time and date is included in the file.
<p><u>Instruments</u> <u>Calibration of Controlling, Monitoring and Recording Instruments.</u></p> <p><u>Furnaces used at a single temperature</u> (3.2.5.5.5): 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; temperature of use and 2 or more points bracketing the temperature of use.</p>	<p>When subject to the necessary field calibration, the MCT4 is suitable for use as defined by clause 3.2.5.5.5.</p> <ul style="list-style-type: none"> • Two types of calibration are available and described in the user manual: <ul style="list-style-type: none"> ○ Calibration Offsets (high & low) ○ Manual Calibration using the Factory Calibration procedure: This requires high accuracy input simulation equipment to properly calibrate to factory standards.
<p><u>Instruments</u> <u>Electronic Records</u></p> <p><u>Electronic Records</u> (3.2.7.1): Electronic records are 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>When using a system (furnace control, recording, monitoring or data acquisition) that creates electronic records shall meet the following requirements as described in the following sections:</p> <ul style="list-style-type: none"> • 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 	<p>The MCT4 is suitable for use as defined by clause 3.2.7.1 and the noted subsections shown in the column to the left.</p>

Requirement	MCT4 Capability
<p><u>Instruments</u> <u>Electronic Records</u></p> <p><u>Altering Electronic Records</u> (3.2.7.1.1): Electronic records cannot be altered without notification.</p>	<p>The MCT4 is suitable for use as defined by clause 3.2.7.1.1</p> <p>The MCT4 electronic records (temperature data log files) are electronically (digitally) signed by the system when the file is closed.</p> <p>If the file is altered an alert is provided when the file is viewed on the MCT4 or Future Design Control's (FDC's) PC software Data File viewer. Additional information is below.</p> <ul style="list-style-type: none"> • When closing a data file, the system electronically signs the file (encrypted signature) with the signature file permanently linked to the data file. • Additional encrypted digital signatures can be added to any closed data file by users with the appropriate security rights • When Data files are viewed on the MCT4 or FDC's PC software Data File Viewer, data files that have been altered will fail digital signature validation.
<p><u>Instruments</u> <u>Electronic Records</u></p> <p><u>Electronic Records Playback without alteration</u> (3.2.7.1.2): The system software and playback utilities shall provide a means to examine and/or compile the record data, but shall not provide any means for altering the source data.</p>	<p>The MCT4 is suitable for use as defined by clause 3.2.7.1.2</p> <ul style="list-style-type: none"> • When viewing a data log file from the MCT4 or FDC's PC software "Data File Viewer" there is no manner to alter the source data. • Both the MCT4 and FDC's PC software Data File Viewer systems check the integrity of the closed data file; any change to a closed data file results in an integrity failure notification.
<p><u>Instruments</u> <u>Electronic Records</u></p> <p><u>Electronic Records Viewing and Copying (file export)</u> (3.2.7.1.3): Provide a method to generate accurate and complete copies of records in both human readable and electronic form suitable for inspection, review, and copying.</p>	<p>The MCT4 is suitable for use as defined by clause 3.2.7.1.3</p> <ul style="list-style-type: none"> • View the data log history on the MCT4 data file History Plot function • Export encrypted data for viewing on a personal computer using the FDC's Data File Viewer. (Data files cannot be altered by FDC's Data File Viewer.) • Data may be exported from the MCT4 via USB, email and FTP functions. • When Data files are opened in FDC's PC software Data File Viewer they may be printed. • Once exported, data files can be converted to Excel spreadsheets for inspection, review and copying. • Data files that have been altered will fail digital signature validation when opened on the MCT4 and FDC's PC software Data File Viewer.

Requirement	MCT4 Capability
<p><u>Instruments</u> <u>Electronic Records</u></p> <p><u>Electronic Records Evidence of User Review (3.2.7.1.3.1):</u> Method to provide evidence the record was reviewed electronically (viewed) or method of printing the record to add a physical marking to indicate the file was reviewed.</p>	<p>The MCT4 is suitable for use as defined by clause 3.2.7.1.3.1</p> <ul style="list-style-type: none"> • Digital Signature(s) provide evidence of user reviewing record(s) on MCT4 or FDC’s PC software Data File Viewer. Additional encrypted digital signatures can be added to any closed data file if 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, email or FTP. Once exported and opened in FDC’s PC based Data File Viewer or other 3rd party software (i.e. excel) the data may be printed, reviewed and physically marked indicating it was reviewed. • If data files are modified in any way their integrity is lost as the digital signature will fail when the file is opened in the MCT4 or FDC’s PC software Data File Viewer.
<p><u>Instruments</u> <u>Electronic Records</u></p> <p><u>Electronic File Protection & Retention for 5-years (3.2.7.1.4):</u> The system will provide file protection, retention and retrieval of accurate records throughout the record retention period of no less than 5-years.</p>	<p>The MCT4 is suitable for use as defined by clause 3.2.7.1.4.</p> <ul style="list-style-type: none"> • Data and other files are saved to a factory supplied 8GB or larger SD card installed on the back of the unit. This SD card’s capacity exceeds the typical storage requirements over a 5-year period. • Ability to export all data records to USB Flash Memory/FTP/Cloud. <ul style="list-style-type: none"> ○ Selectable to copy only or copy and delete files from the MCT4 • Once exported Data files can be transferred to longer lasting storage media labeled appropriately. • FDC’s PC software Data File Viewer validates file integrity and allows viewing without altering the original data file • If data files are modified in any way, their integrity is lost as the digital signature will fail when the file is opened in the MCT4 or FDC’s PC software Data File Viewer.

Requirement	MCT4 Capability
<p><u>Instruments</u> <u>Electronic Records</u></p> <p><u>Electronic Records Security/Password Protection (3.2.7.1.5):</u> The system shall provide methods (i.e. passwords) to limit system access to only individuals whose authorization is documented.</p>	<p>The MCT4 is suitable for use as defined by clause 3.2.7.1.5 when security is enabled and setup appropriately.</p> <ul style="list-style-type: none"> • Select User Group Type/Levels: Each user is assigned to a one of four user groups or types. Each of the four groups can represent a different level of privileges and security • Username and Password: assign a unique username and password for each user. • Permissions for each user group can be individually enabled and disabled for every major function of the system. • Optionally enable re-authentication to enforce security even if a user forgets to log-off. Re-authentication prompts the user for their username and password before changing any process control variable or other function. • Audit Trail File (when enabled): <ul style="list-style-type: none"> ○ All operator actions are recorded in a secure (encrypted) audit trail file including date/time stamp the action occurred. ○ The integrity of the Audit Trail files are verified when opened in the MCT4 or FDC's PC software Data File Viewer
<p><u>Thermal Processing Equipment</u></p> <p><u>Instrumentation used to Control, Record or Indicate the desired temperature (3.3.1):</u></p> <p>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.</p> <p>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.</p>	<p>When subject to the necessary field calibration, the MCT4 is suitable for use in Nadcap applications in all furnace classes as defined in AMS2750E clause 3.3.1</p> <ul style="list-style-type: none"> • Two types of calibration are available and described in the user manual: <ul style="list-style-type: none"> ○ Calibration Offsets (high & low) ○ Manual Calibration using the Factory Calibration procedure: This requires high accuracy input simulation equipment to properly calibrate to factory standards. • Offsets: the MCT4 provides a means, documented in the user manual, to introduce offsets for each input in 0.1 degree increments (F or C). • Offsets: when in the calibration mode where offsets are entered, the offset values are shown digitally providing a means to document and reintroduce any intentional offset(s). • Offsets: the MCT4 allows offset parameters as defined in Table 6 (maximum permitted adjustment (offset)).

Requirement	MCT4 Capability
<p><u>System Accuracy Tests (SATs)</u></p> <p><u>Calibration Limitations (3.4.5.6):</u> Adjustment of the control or recording instrument calibration is permitted with the maximum adjustment limitations of Table 6 or 7.</p>	<p>The MCT4 is suitable for use as defined by clause 3.4.5.6.</p> <ul style="list-style-type: none"> • The MCT4 allows entry and display of offset parameters meeting the requirements. .
<p><u>Temperature Uniformity Surveys (TUS)</u></p> <p><u>Temperature Uniformity Survey Report (3.5.21.2):</u> Although not a required part of the uniformity survey report, the following shall be accessible on site:</p> <ol style="list-style-type: none"> Control instrument tuning parameters. 	<p>The MCT4 is suitable for use as defined by clause 3.4.5.6.</p> <ul style="list-style-type: none"> • The MCT4 tuning parameters may be viewed if so configured. • Access to and changing tuning parameters may be impacted by security settings and user rights.

Q & A: Electronic Records and Digital Signatures

Question (Electronic Records)	Answer
Was an established software development life cycle used?	<p style="text-align: center;">Yes</p> <p>The MCT4 was designed and validated using a full SDLC “risk” based system to include detailed specifications and validation of all software.</p>
Have code reviews been conducted?	<p style="text-align: center;">Yes</p> <p>Code reviews performed throughout validation cycle.</p>
Has System Testing been conducted?	<p style="text-align: center;">Yes</p> <p>All system testing complete during DVR (design verification release) validation testing and user field testing.</p>
Has Data Conversion testing been conducted?	<p style="text-align: center;">Yes</p> <p>Export data testing completed with signature verification of exported data performed/documented during validation.</p>
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.)?	<p style="text-align: center;">Yes</p> <p>Full security validation performed to include user login entry data, field formatting, successful/failed login attempts and audit trail functionality performed/documented during validation.</p>
Can a copy of a single record (in electronic format) be supplied to an inspector?	<p style="text-align: center;">Yes</p> <p>Export data testing completed with signature verification of exported data.</p>
Is there test evidence for the audit trail functionality	<p style="text-align: center;">Yes</p> <p>Full audit trail functionality testing performed/documented during validation.</p>
Does test evidence exist to demonstrate the operational checks (that is, sequences of events within the system)?	<p style="text-align: center;">Yes</p> <p>Operational check testing (include user re-authentication for operational steps) performed/documented during validation.</p>
Does test evidence exist to demonstrate the use of the authority checks (based on role-based permissions)?	<p style="text-align: center;">Yes</p> <p>All user and group authentication checks performed/documented during validation.</p>

Question (Digital Signatures)	Answer
Does test evidence exist for the signature manifestation (full name, date and time)?	<p style="text-align: center;">Yes</p> Full digital signature functionality testing performed/documented during validation.
Is the transfer of the signature to another record prevented?	<p style="text-align: center;">No</p> 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 fail during signature verification.
Does test evidence exist to document signature actions are captured in the audit trail?	<p style="text-align: center;">Yes</p> Full digital signature functionality testing performed/documented during validation.
Does test evidence exist to prove the enforcement of unique username and id?	<p style="text-align: center;">Yes</p> 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 MCT4 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?	<p style="text-align: center;">No</p> 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?	<p style="text-align: center;">No</p> 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)?	<p style="text-align: center;">Yes</p> Password ageing functionality testing performed/documented during validation
Does test evidence exist to demonstrate detection of attempts of unauthorized access?	<p style="text-align: center;">Yes</p> 3 attempts max. 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?	<p style="text-align: center;">Yes</p> Security/User functionality testing performed/documented during validation