

MCT4_MCTB

AMS2750F Guidelines

**How the MCT4_MCTB controllers along with end users
Standard Operating Procedures (SOPs)
meet the guidelines specific to
control, Monitoring and Recording Instruments
for
Temperature Accuracy and Electronic Records**

Overview

AMS 2750F 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_MCTB along with an end users validated Standard Operating Procedures (SOPs) can meet the AMS2750F guidelines for “Controllers, Monitors and Recorders/Data Acquisition Systems” specific to Accuracy, Offsets, Electronic Records, Security and the specific SAT and TUS requirements described below.

AMS2750F Section	Topic	MCT4_MCT B Meets the Guidelines
Instrumentation 3.2.1.3	Calibration accuracy (+/- 2.0°F or 1.1°C) in accordance of Table 7	√ and SOP
Control, Recording and Over-Temperature Instruments: 3.2.3/.1/.2/.4	Control, Recording and Over-Temperature Instruments: Digital Display Resolution of 0.1°C or F.	√
Control, Recording and Over-Temperature Instruments: 3.2.3.19	Digital Recording timing shall be calibrated annually to +/- 1 minute/hour	√ and SOP
Electronic Records 3.2.4.2	Electronic Records: a. Electronic records cannot be altered without detection b. System software and playback utilities to examine data but not allow alteration c. Copies of records in readable & electronic form to inspect, review and duplicate d. Provide evidence the record was reviewed or provide method of printing for physical marking it was reviewed e. Retention and retrieval of electronic records f. Hardware/Software shall operate through retention period g. Security - Password protection	√ and SOP
Software Revision 3.2.4.3	Software revisions are verified to continue compliance and once installed to alter recipes or other means to control thermal processing parameters.	√ and SOP
Instrument Corrections and Modification Offset 3.2.6.1 / .2 / .4 / .5	Maximum Cumulative correction Offsets for Thermal Processing Equipment Instruments or Refrigeration and Quench Instruments	√ and SOP
Requirements for Furnace Instrumentation / 3.3.2	Table 12 Instrumentation Type Requirements - Furnace Classes	√ and SOP
Thermal Processing Equip 3.3.3.1 / .2 / .4	Thermal Processing Equipment: All Refrigeration and Quench Equipment require Recorder	√ and SOP

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_MCTB Capability
<p><u>Instrumentation</u></p> <p><u>Calibration Accuracy (3.2.1.3)</u> Calibration accuracy for Controlling, Monitoring or Recording Instrument shall be in accordance with Table 7.</p> <p>Table 7:</p> <ul style="list-style-type: none"> • 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. 	<p>When subject to the necessary field calibration, the MCT4_MCTB is suitable for use as defined by clause 3.2.1.3</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>Control, Recording and Over-Temperature Instruments</u></p> <p><u>Temperature Display Increments (3.2.3 / 3.2.3.1 / 3.2.3.2):</u> All control, recording and over-temperature instruments shall be digital. Digital recording instruments will have a minimum readability of 0.1°F or C.</p>	<p>The MCT4_MCTB is suitable for use as defined by clause 3.2.2.3.1.</p> <ul style="list-style-type: none"> • The MCT4_MCTB is configurable to display and data log temperatures in 1.0 or 0.1 degrees C or F.
<p><u>Control, Recording and Over-Temperature Instruments</u></p> <p><u>Offsets (3.2.6.1):</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_MCTB is suitable for use as defined by clause 3.2.4.</p> <ul style="list-style-type: none"> • The MCT4_MCTB 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_MCTB allows offset parameters as defined in Table 6 (maximum permitted adjustment (offset)).

Requirement	MCT4_MCTB Capability
<p><u>Electronic Records</u></p> <p><u>Electronic Records</u> (3.2.4.2): 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"> • 3.2.4.2 - a • 3.2.4.2 - b • 3.2.4.2 - c • 3.2.4.2 - d • 3.2.4.2 - e • 3.2.4.2 - f • 3.2.4.2 - g 	<p>The MCT4_MCTB is suitable for use as defined by clause 3.2.4.2 and the noted subsections shown in the column to the left.</p>
<p><u>Electronic Records</u></p> <p><u>Altering Electronic Records</u> (3.2.4.2 - a): Create records that cannot be altered without detection.</p>	<p>The MCT4_MCTB is suitable for use as defined by clause 3.2.4.2 - a.</p> <p>The MCT4_MCTB 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_MCTB 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_MCTB or FDC's PC software Data File Viewer, data files that have been altered will fail digital signature validation.

Requirement	MCT4_MCTB Capability
<p><u>Electronic Records</u></p> <p><u>Electronic Records Playback without alteration</u> (3.2.4.2 - 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>	<p>The MCT4_MCTB is suitable for use as defined by clause 3.2.4.2 - b.</p> <ul style="list-style-type: none"> • When viewing a data log file from the MCT4_MCTB or FDC’s PC software “Data File Viewer” there is no manner to alter the source data. • Both the MCT4_MCTB 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>Electronic Records</u></p> <p><u>Electronic Records Viewing and Copying (file export)</u> (3.2.4.2 - c): Provide ability to generate accurate and complete copies of records in both human readable and electronic form suitable for inspection, review, and duplication.</p>	<p>The MCT4_MCTB is suitable for use as defined by clause 3.2.4.2 - c.</p> <ul style="list-style-type: none"> • View the data log history on the MCT4_MCTB 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_MCTB 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_MCTB and FDC’s PC software Data File Viewer.

Requirement	MCT4_MCTB Capability
<p><u>Electronic Records</u></p> <p><u>Electronic Records Evidence of User Review (3.2.4.2 - d):</u> 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>	<p>The MCT4_MCTB is suitable for use as defined by clause 3.2.4.2 - d.</p> <ul style="list-style-type: none"> • Digital Signature(s) provide evidence of user reviewing record(s) on MCT4_MCTB 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_MCTB or FDC's PC software Data File Viewer.
<p><u>Electronic Records</u></p> <p><u>Electronic File Protection & Retention for 5-years (3.2.4.2 - e):</u> Support protection, retention, and retrieval of accurate records throughout the record retention period.</p>	<p>The MCT4_MCTB is suitable for use as defined by clause 3.2.4.2 - e.</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_MCTB • 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_MCTB or FDC's PC software Data File Viewer.

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<p><u>Electronic Records</u></p> <p><u>System will operate through the Retention Period (3.2.4.2 - f):</u> Ensure that the hardware and/or software shall operate throughout the retention period as <u>specified in 3.7</u></p> <p><u>3.7: Records</u> <i>3.7.1: All records of sensor calibration, and instrument calibration, SAT, and TUS in addition to any calibration, SAT, and TUS failures shall be available for inspection and shall be maintained for not less than 5-years.</i></p>	<p>The MCT4_MCTB is suitable for use as defined by clause 3.2.4 - f.</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_MCTB • 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 <p>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_MCTB or FDC's PC software Data File Viewer.</p>
<p><u>Electronic Records</u></p> <p><u>Electronic Records Security/Password Protection (3.2.4.2 - g):</u> Provide methods of protection, such as a password, to limit system access to only individuals whose authorization is documented.</p>	<p>The MCT4_MCTB is suitable for use as defined by clause 3.2.4.2 - g 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_MCTB or FDC's PC software Data File Viewer

Requirement	MCT4_MCTB Capability
<p><u>Electronic Records</u></p> <p><u>Software Revisions effect with Continued Compliance with the Material or Process Specifications (3.2.4.3)</u></p> <p>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 MCT4_MCTB is suitable for use as defined by clause 3.2.4.3 when a software revision is installed via an “updater” program. The software revision installed by the “updater” will add functions and/or correct identified deficiency (i.e. bug) but does not affect the MCT4_MCTB configuration or core functions.</p> <p>Further details on MCT4_MCTB validation is described in the Q&A section of this document with a summary below.</p> <p><i>Upon release a software revision document is available noting the changes.</i></p> <p><i>The MCT4_MCTB was designed and validated using a full SDLC “risk” based system to include detailed specifications and validation of all software.</i></p> <p><i>MCT4_MCTB software revisions follow the same validation protocol used in its initial design.</i></p> <p><i>Code reviews are performed throughout validation cycle. All system testing complete during DVR (design verification release) validation testing and user field testing.</i></p>
<p>General Instrument Correction & Modification Offset</p> <p>Instrument Corrections and Modification Offset Requirements (3.2.6.1 / .2 / .4 / .5 / .6)</p> <p>3.2.6.1.2: The maximum cumulative correction offset shall not exceed the uniformity tolerance for the thermal processing equipment or +/1 5.0°F or +/- 2.8°C for refrigeration and quench instruments</p> <p>3.2.6.4: Controlling instrument modification offsets for TUS shall not exceed the allowances in Tables 18 or 19. SAT modification offsets are not allowed.</p> <p>3.2.6.1.5: Control and recording instrument correction offsets for SAT shall not exceed the allowances in Tables 18 & 19. TUS modification offsets are not permitted on recorder channels other than for the channel recording the control sensor temperature.</p> <p>3.2.6.1.6: For load sensor systems used in production, correction offsets are allowed, but not modification offsets.</p>	<p>When appropriately equipped for the number of temperature sensor inputs, control loops and subject to the necessary field calibration, the MCT4_MCTB is suitable for use as defined by clause 3.2.6.1 / .2/ .4 / .5 / .6</p>

Requirement	MCT4_MCTB Capability
<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 Table 11 and are based on the furnace class specified. When not specified, furnace class shall meet the temperature uniformity requirements established in the governing specification for the material being processed. Instrumentation types are defined by the level of instrumentation used to control, record or indicate the desired temperature.</p> <p>Intervals for controlling and recording instrument calibration, system accuracy tests, temperature uniformity surveys, are based on the combined furnace class and instrumentation type slated in Tables 7, 14, 15, 18 or 19.</p>	<p>When subject to the necessary field calibration, the MCT4_MCTB is suitable for use in applications in all furnace classes as defined in AMS2750F 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_MCTB 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_MCTB allows offset parameters as defined in Table 6 (maximum permitted adjustment (offset)).
<p><u>Requirements for Furnace Instrumentation (3.3.2)</u></p> <p><u>Table 12 – Instrumentation type requirements</u></p> <ul style="list-style-type: none"> - The temperature indicated by the control sensor in each control zone shall be recorded by a recording instrument - 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 TUS. - At least one recording load sensor in each control zone - Each control zone shall have over-temperature protection <ul style="list-style-type: none"> ○ 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+ in the proper location. ○ 	<p>When appropriately equipped for the number of temperature sensor inputs, control loops and subject to the necessary field calibration, the MCT4_MCTB is suitable for use as defined by clause 3.3.2, Table 12.</p>
<p><u>Thermal Processing Equip (3.3.3.1 / .2 / .4</u></p> <p>All refrigeration equipment shall have a temperature control and equipped with a temperature recording instrument where time-at-temperature (minimum, maximum or both) is required</p> <p>Quench systems (immersion or spray) shall be equipped with a sensor that is recorded by recording instrument.</p>	<p>The MCT4_MCTB is suitable for use as defined by clauses 3.3.3.1 / .2 / .4.</p>

Requirement	MCT4_MCTB Capability
<p><u>System Accuracy Tests (SATs)</u></p> <p><u>Allowable Instrument Correction (offsets) include</u> (3.4.4.4.1 / .2):</p> <p>3.4.4.4.1: Internal modification offsets applied to the control and control recording channel instrument solely to correct a skewed TUS distribution.</p> <p>3.4.4.4.2: A previously documented and specified correction offset of the control or recording instrument to correct an SAT difference.</p>	<p>The MCT4_MCTB is suitable for use as defined by clause 3.4.4.4.1 / .2.</p> <ul style="list-style-type: none"> • The MCT4_MCTB allows entry and display of offset parameters meeting the requirements.
<p><u>Temperature Uniformity Surveys (TUS)</u></p> <p><u>Temperature Uniformity Survey Report (3.5.2):</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"> a. Control instrument tuning parameters. 	<p>The MCT4_MCTB is suitable for use as defined by clause 3.5.2.</p> <ul style="list-style-type: none"> • The MCT4_MCTB 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> The MCT4_MCTB 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?	<p style="text-align: center;">Yes</p> Code reviews performed throughout validation cycle.
Has System Testing been conducted?	<p style="text-align: center;">Yes</p> All system testing complete during DVR (design verification release) validation testing and user field testing.
Has Data Conversion testing been conducted?	<p style="text-align: center;">Yes</p> 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.)?	<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.
Can a copy of a single record (in electronic format) be supplied to an inspector?	<p style="text-align: center;">Yes</p> Export data testing completed with signature verification of exported data.
Is there test evidence for the audit trail functionality	<p style="text-align: center;">Yes</p> 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)?	<p style="text-align: center;">Yes</p> 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)?	<p style="text-align: center;">Yes</p> All user and group authentication checks performed/documented during validation.

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_MCTB 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