Regulatory systems overview **Memograph M RSG45 and Field Data Manager (FDM)**

For PMO regulatory information per PMO 2023 revision appendix H section V

Endress+Hauser

People for Process Automation

Introduction and system description

Memograph M RSG45 data manager hardware and Field Data Manager (FDM) software by Endress+Hauser enables reliable, secure measured data recording, electronic record management, batch report creation, archiving and transmission as specified in the FDA 21 CFR Part 11 and compliance to PMO and process authority requirements. Recorded data is stored on Memograph M RSG45 in internal memory (SD card) or on removable USB memory stick. The standard 256 MB internal memory holds approximately six weeks of data when used as STLR/ SFLR with a one second recording interval. The FDM reporting software is installed on local SQL server and connected to Memograph M RSG45 via LAN (EtherNet TCP/IP) for instant access to current and recorded data. Operators can enter annotations directly on recorders or on local server workstations. Records and annotations are available directly on Memograph M RSG45 for review and approval. The FDM provides a platform for supervisors, regulatory, quality, etc., to access records and annotations as well as workflow to approve and save records securely on company servers. Printing of records is available.

Typical applications are:
- Continuous pasteurization in HTST, UHT and Aseptic
- ESL Applications
- Juice Pasteurization
- Egg Pasteurization
- Cold Product Recording
- Product tank/silo temperature and level
- Clean-In-Place (CIP)
- Clean-Out-of-Place (COP)
- Retort, low-acid
- General Process Recording and Monitoring

Compliance with the general requirements of FDA 21 CFR, Part 11 (electronic records) and PMO Appendix H, Section V

The recording system, which is comprised of Memograph M RSG45 and FDM software, fulfills the general requirements of FDA 21 CFR, part 11 related to system security, data traceability and integrity. Further details are laid out in the white paper:
Memograph M RSG45 and FDM FDA 21 CFR, part 11 (supplement WP01028L).

Data integrity and system overview

The graphic data manager Memograph M RSG45 securely records, archives, stores and transmits all relevant information it reads from the connected device(s). Measured values are recorded, limit values are monitored, and information is securely stored in the internal system memory.

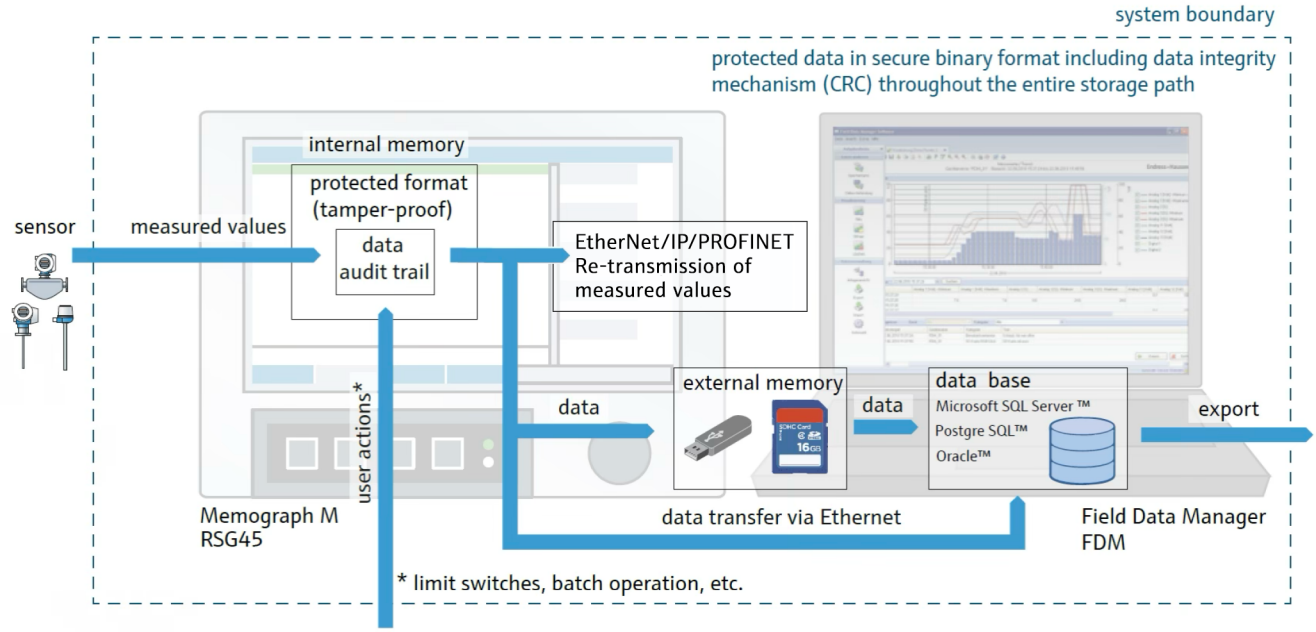

Figure 1: Data integrity from sensor to batch reporting

The data — as defined by measured values and electronic records of audit trail per FDA 21 CFR part 11 — is stored in a proprietary binary file format to protect against tampering. The integrity of the electronic records in the data manager is ensured by means of a cyclic redundancy check (CRC). The CRC code is part of the raw data file.

Re-transmission: Memograph M RSG45 has options for 2 x 4-20mA retransmission outputs. Alternatively, EtherNet/IP/PROFINET can be used for re-transmission of all inputs, outputs and states. EtherNet/IP is a protocol for cyclic data transfer to the PLC. EtherNet/IP/PROFINET are communication protocol purely for data exchange, programming changes are not possible via these protocols.

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1. User administration according to FDA 21 CFR Part 11

For PMO applications, it is mandatory to use the user administration according to FDA 21 CFR, Part 11 which is implemented in the Memograph M RSG45.

Memograph M RSG45 manages 50 user accounts in five authorization levels (Administrator, Main User, Operator 1/2/3) and assigns access rights to the respective users. For PMO applications, the only user roles that will be applied are “Admin” and “Main User.” We recommend two or more individuals with “Admin” rights. “Main Users” can be added/deleted by an administrator without breaking the regulatory seal. The “Admin” level can only be changed when removing regulatory seal.

Table 1 FDA user roles and access authorization

User Authorization per 21CFR part 11	Admin	Main User	Operator 1	Operator 2	Operator 3
Set-up change	Yes	No	No	No	No
Set limit value	Yes	No	No	No	No
Select preset limit value	Yes	Yes	No	No	No
Enter Text	Yes	Yes	Yes	No	No
Acknowledge events	Yes	Yes	Yes	Yes	No

Setup change: Change the parameter settings for Memograph M RSG45. For units with the regulatory seal installed, the seal must be broken to make programming changes and the lock jumper removed, and the user level administrator logged in.

Text entries: Text entries (annotations) can be entered at any time during or at the end of production.

2. Primary saving of data to server or PC (FDM)

Memograph M RSG45 only works in combination with FDM and uses proprietary binary file format to prevent user manipulation. To transfer Memograph M RSG45 data to FDM it is recommended to use the EtherNet interface. This will provide automatic, fast and reliable data transfer to on premise PC or server. Memograph M RSG45 has an onboard 256 MB RAM memory in addition to a 1 GB SD card. The onboard RAM hold > four weeks of data for a typical STLR/SFLR (number of channels and save cycle dependent) The SD card adds additional onboard back-up in event of catastrophic failure. In event of loss of/interruption of the Ethernet connection to PC/server, data transfer initiates immediately as soon as connection is re-established. Any interruption is captured in the audit trail.

Note: Per PMO Appendix H, Section V: Any computer required making a public health safety report, including data collection computers, data storage computers or report servers shall be powered with an Uninterruptible Power Supply (UPS) capable of maintaining power to the computerized data collection, storage and reporting system for twenty (20) minutes.

3. Secondary data backup via SD card or USB-stick

The primary method for data storage is via continuous connection to FDM software via Ethernet TCP/IP. However, a secondary method is to use a removable USB stick if desired. Without affecting the internal memory, data packets are copied to the internal SD card automatically, block by block (min. 1 x per day, midnight). Checksum tests are also performed automatically to ensure data has been written without errors.

If needed, a manual save of data files can be executed using a USB stick.

4. FDM system requirements

For installation and use of the software, the following hardware and software requirements must be fulfilled.

Hardware prerequisites for FDM software:
- PC with PentiumTM 4 (≥2 GHz)
- PC with PentiumTM M (≥1 GHz)
- PC with AMDTM (≥1.6 GHz)
- At least 1 GB RAM cache
- At least 20 GB free hard disk space
- Display resolution at least 1024 x 800 pixel
- CD/DVD drive (For computers without a drive, the software can also be downloaded via the Endress+Hauser Software Portal (see chapter 5, Installation)

Operating system/software for FDM software:
- MicrosoftTM WindowsTM 2003 Server R2 SP2 Standard, Enterprise
- MicrosoftTM WindowsTM Server 2008, 2012, 2016, 2019
- MicrosoftTM XP SP3
- MicrosoftTM VistaTM
- Windows 7TM
- Windows 8TM Windows 8.1TM
- Windows 10TM
- WindowsTM .NET 2.0 SP1

5. Local server setup and configuration

A written user's guide of the computerized data collection, storage and reporting system shall be provided and will explain the system's architecture, the software used and the sensors or instruments monitored. This overview may be presented in text or in a graphical representation. A copy of this overview shall be maintained at the discretion of the regulatory agency. This document shall bear the name of the identified representative from the milk plant assigned to administrate this procedure and be available for review at the milk plant by the regulatory agency and FDA.

This documentation shall explain:
a. System's architecture, the software used and the sensors or instruments monitored;
b. Reporting interface of the computerized data collection, storage and reporting system;
c. Backup procedure for ensuring the safe storage of the public health safety data of all reports;
d. Procedure for any changes or maintenance to the instrumentation, sensors, hardware or computers. This procedure will explain how the plant will ensure that when a physical change occurs the information affected has been checked for accuracy; and
e. Listing and explanation of the reports available on the system, instructions on how to access the reports and examples of each report with a description of their content.

A written record shall be maintained by the milk plant identifying any changes or updates to the computerized data collection, storage and reporting system, software, drivers, networking or servers in order to assure the collection, storage or reporting of any data needed for compliance has not been compromised. This document shall bear the name of the representative from the milk plant assigned to administer this procedure and be available for review at the milk plant by the regulatory agency and FDA.

Written record

Describe local server setup, change management, procedure and location for back-up.
Space for illustration.

Item	Description	Change/maintenance/ calibration per SOP #
FDM Software revision	1.6.8 and higher	
RSG45 Firmware revision	ENX200A 2.06.xx	
Server information: (Location, description)		
Sensor 1 monitored: (Example: Temperature sensor model TM402, range 32-300 °F)		
Sensor 2 monitored		
Sensor 3 monitored		
Sensor 4 monitored		
Sensor 5 monitored		
Sensor 6 monitored		

I verify that information related to recorder (Model, Ser # and TAG) _____ is accurate.

Processor _____

Name _____

Company _____

Signature _____

Date/place _____

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