Compliance solutions
Memograph M RSG45 and Field Data Manager (FDM)

For instrumentation and paperless recording of regulatory, quality and safety-related process parameters. Selecting the right options for your application according to 21CFR part 113 and/or PMO (Pasteurized Milk Ordinance) 2023 Rev.
RSG45 STLR/SFLR M-b-385

Endress+Hauser
People for Process Automation

Introduction and system description

Memograph M RSG45 data manager hardware and FDM (Field Data Manager) software by Endress+Hauser enables reliable, secure measured data recording, electronic record management, archiving and transmission as specified in the FDA 21 CFR Part 11 and compliance with PMO (Pasteurized Milk Ordinance) and process authority requirements. Recorded data is stored on Memograph M RSG45 in internal memory. The 1GB internal memory holds approximately 24 weeks of data when used as STLR/SFLR with a one-second recording interval. The FDM (Field Data Manager) 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 the recorder or on the local server workstation. Records and annotations are available directly on Memograph M RSG45 for review and approval. The FDM provides a platform for supervisors, regulatory and quality to access records, make annotations as well as workflows to approve and save records securely on company servers. Printing of records is also possible.

Typical applications are:

PMO (Pasteurized Milk Ordinance)

- Continuous pasteurization in HTST, UHT and aseptic recorder/controller
- ESL applications
- Cold product recording
- Product tank/silo temperature and level
- Clean-In-Place (CIP)

CFR 21 part 13 and general process recording and monitoring

- Juice pasteurization
- Egg pasteurization
- Clean-Out-of-place (COP)
- Retort, low-acid

Compliance to the general requirements of FDA 21 CFR Part 11 (electronic records) and PMO appendix H section V

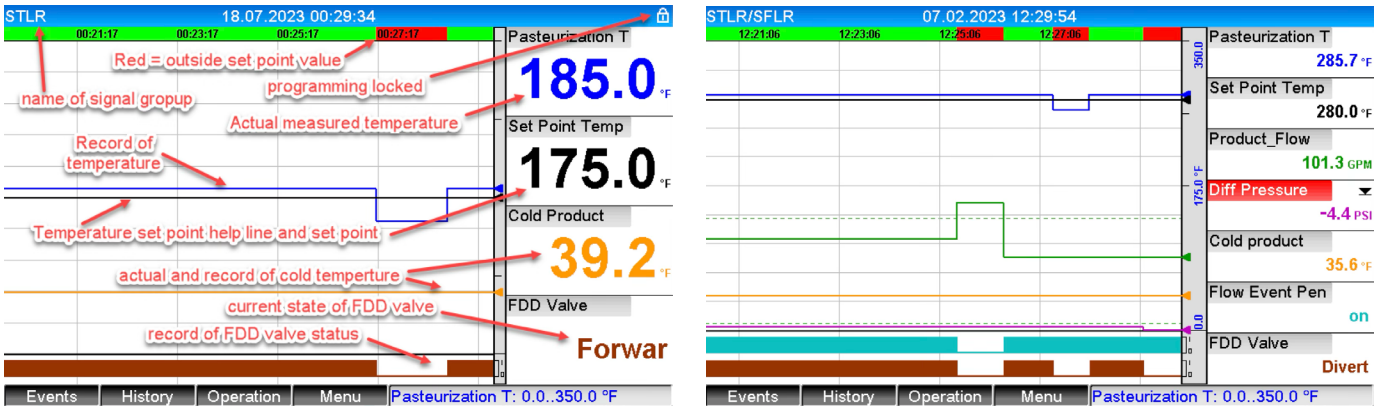

Figure 1: Example of recorder screen when used as STLR (Safety Thermal Limit Recorder) or combined STLR,SFLR + differential pressure switch

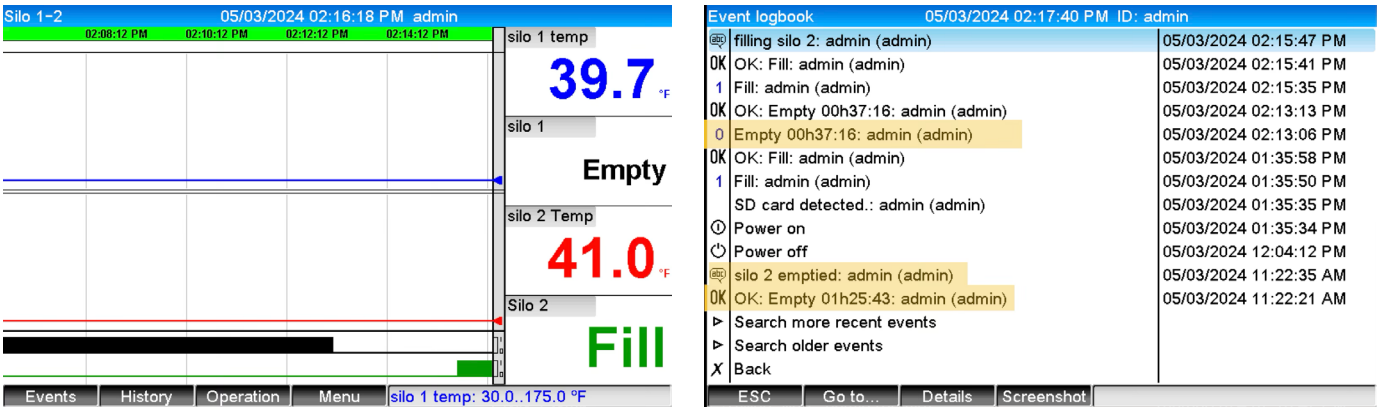

Figure 2: Example of recorder screen when used for milk silo temperature records

The recording system, which is comprised of Memograph M RSG45 and FDM (Field Data Manager) 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 whitepaper: *Memograph M RSG45 and FDM FDA 21 CFR part 11* (supplement WP01028L) and have been reviewed per PMO M-b-385 as recorder controller.

Data integrity and system overview

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

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

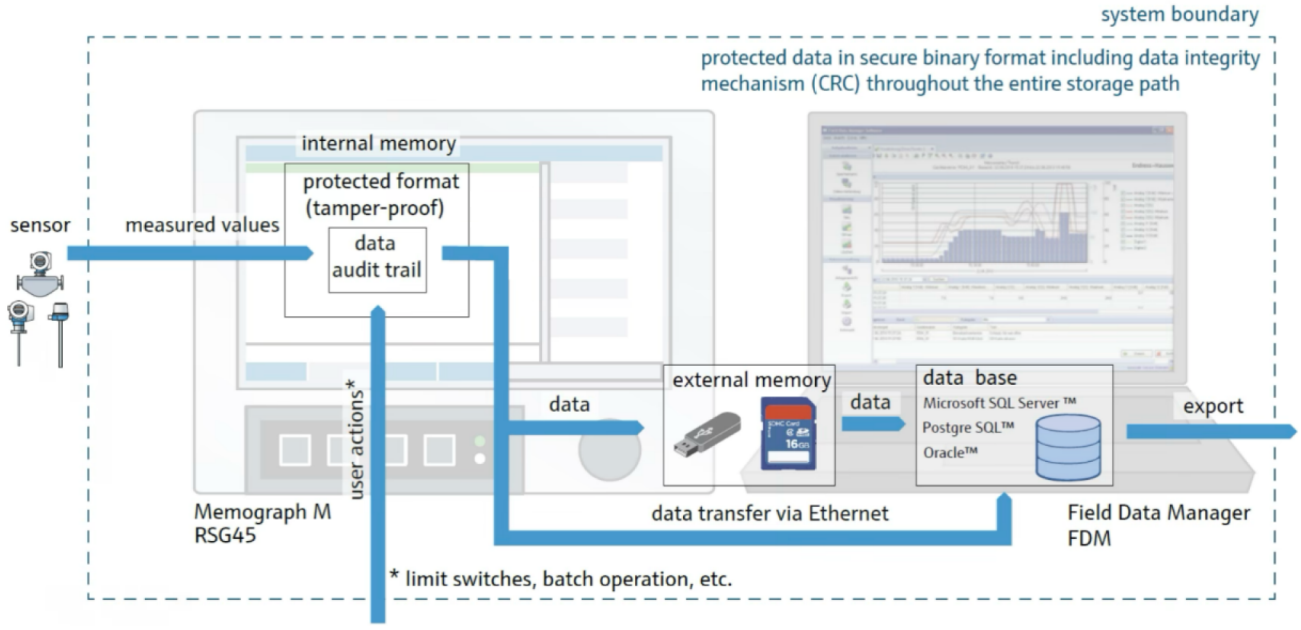

Figure 3: Data integrity from sensor to batch reporting

Table of contents

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 Memograph M RSG45.

Memograph M RSG45 accommodates 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 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 or removed by the administrator without breaking the regulatory seal. “Admin” level can only be changed when removing a regulatory seal.

Table 1 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: For units with regulatory seals installed, the seal must be broken, the lock jumper removed and the user-level administrator must log in to make programming changes. Text entries (annotations) can be entered any time after logging on.

2. Saving of recorded data to server or PC (FDM)

Memograph M RSG45 works only with FDM and uses a proprietary binary file format to prevent manipulation per 21CFR part 11. Transfer of Memograph M RSG45 data to FDM via the EtherNet TCP/IP interface is set to automatically save every one to five minutes (admin configurable). This will provide automatic, fast and reliable data transfer to an on-premises PC or server. Memograph M RSG45 has onboard RAM and a 1GB backup memory; the onboard RAM holds <four weeks of data for a typical STLR/SFLR (number of channels and save cycle dependent). The 1 GB SD card adds approximately 24 weeks of onboard backup in the event of catastrophic failure. In the event of loss or interruption of the Ethernet connection to the PC/server, data transfer initiates immediately after the connection is re-established. Any interruption is captured in the audit trail.

Note: per PMO appendix H section V: Any computer required to make 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. Recorder configuration programming

Memograph M RSG45 needs to be programmed for the application. This involves channel identification, pen assignments, display features, setpoints and other application specific functions. Endress+Hauser offers programming support. Once programmed, the program file can be stored on PC, USB drive or other memory media. In the event of recorder replacement or duplicate installation, the program is simply downloaded to the recorder in a matter of seconds.

4. FDM (Field Data Manager)

FDM software MS21 is downloaded via the Endress+Hauser Software Portal. MS21 allows up to five concurrent users and an unlimited number of Memograph M RSG45s can be connected. See MS21 installation and setup instructions KA00466C07A2 page 27 onward for details.

5. PMO order options

Depending on the application, specific options are required or not permitted; tables 2-4 below guide option selection. Note that tables show a reduced view of options; see the website configuration tool for full options.

5.1. Memograph M RSG45 recorder

Memograph M RSG45 can accommodate up to 20 analog channels grouped in blocks of four input cards. For a typical STLR/SFLR recorder, four channels would typically be sufficient. (1 x hold temperature, 1 x flowmeter and one for a cold product).

Input slot five option “D” must be selected if 4-20mA signal retransmission is required (max 2 x 4-20mA). Retransmission is also permitted via EtherNet/IP “D” or PROFINET “E” in feature 100. The EtherNet/IP write function is blocked when unit is sealed.

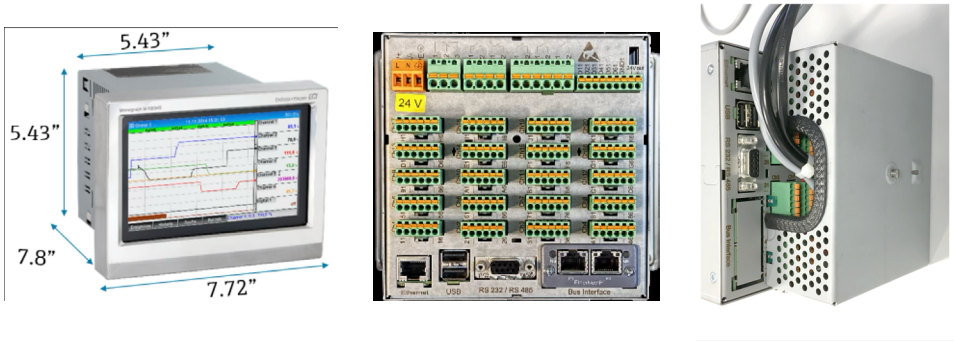

Figure 1: Memograph M RSG45 SS front/back and regulatory cover

In feature 570 “service,” the “H9” option must be selected. This provides the firmware designed and required for PMO applications as well as the M-B number printed on the nameplate for easy state identification.

Memograph M RSG45 can also be used to capture regenerator differential pressure(s) and DRT (Digital Reference Thermometer), and additional channels are needed to accommodate.
For milk silo applications, we recommend max 12 silos per recorder. Math channels limit this to visualize and assign alarms.

For PMO STLR/SFLR applications, the analog inputs must be used to remain compliant. HART communication option is not permitted on PMO STLR/SFLR inputs. For other applications, the EtherNet/IP channels can be used. This increases the channels to max 40.

5.2 Temperature

iTHERM TM311 compact temperature sensor is intended to be used in combination with the M12 lock collar; the lock accommodates the regulatory seal and prevents tampering/disconnection of the sensor from wring. Direct immersion, THERM TipSens and 3-A options are required.

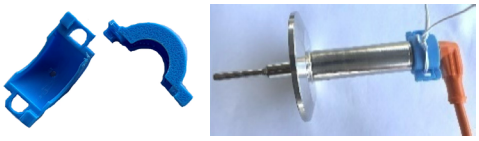

Figure 2: M12 lock collar + installation on TM311 for illustration of regulatory seal

5.3 Pressure (differential pressure across regeneration)

Cerabar PMP43 or Cerabar PMP23 pressure transmitter sensors are intended to be used with the M12 lock collar; the lock accommodates the regulatory seal and prevents tampering/ disconnection of the sensor. 3-A and the version without touch display must be selected — option "G" or "H" in feature 030 on PMP43.

5.4 Electromagnetic flow – timing meters

The FDA has issued "M-b" letters (M-b-379, 380 and 381) verifying that Proline Promag H 100/300 and 500 series meet the intent of the Pasteurized Milk Ordinance (PMO). It can be found at gams.fda.gov, then filter by M-b and search. Endress+Hauser M-bs are also available for download on www.us.endress.com on product web pages under respective model certificates. The letter outlines the model and allowable options and programming required for implementing Proline Promag H for electromagnetic flowmeter-based timing system for HTST pasteurizer or aseptic processing systems in accordance with PMO 2017 revision.

Basic meter option requirements:
- 4-20mA output must be used (EtherNet/IP port is locked)
- SS housing must be selected (or remote aluminum for H500)
- Optional display is ok, WLan is not permitted
- Cable gland or M12 lock must be used if M12 quick disconnect is selected
- 3-A is required

No remote programming access is allowed (i.e., HART must be disabled before sealing unit). The covers provide a means to apply a regulatory seal on the transmitter to prevent anyone from tampering with the setup (PMO locking kit). There is no local programming capability available once the transmitter has been sealed.

The locking kit can be applied to the stainless-steel housing for Proline Promag H 100/H 300 or to the remote wall-mounted electronics version (H 500). Kit is also applicable for the older 50H/53H with SS housing.
- Locking kit for Promag H – PMO regulatory seal (contains screws and display key cover), Endress+Hauser Part # 71433963 (DTSP-AT1XZ8 - TSP 71417487)

Links to PMO review letters
Promag H 100, Promag H 300, Promag H 500

Click instrument links above or visit www.us.endress.com
- Navigate to the instrument page of the flowmeter you are looking for (Promag H 100/300/500)
- Scroll down and select "Certificates" as the download type under the Documents/Manuals drop-down list
- Select "Food Safety" under the filter drop-down list
- Select PMO document
- Click "Download" to access the PMO

Yes	order option mandatory for PMO applications	
Ok	order option allowed for PMO applications	
No	order option not allowed for PMO applications	

Feature	RSG45	Description	PMO HTST	PMO UHT/ESL	PMO Milk Silo Temperature	PMO CIP	Retort	Egg	Aseptic	General recording	comment
010		**Approval:**									
010	AA	Non-hazardous area	Ok	Ok	Ok	Ok	Ok	Ok	Ok	Ok	Preferred
020		**Power Supply:**									
020	1	100-230VAC (+/-10%)	Ok	Ok	Ok	Ok	Ok	Ok	Ok	Ok	
020	2	24V (-10%, +15%) AC/DC	Ok	Ok	Ok	Ok	Ok	Ok	Ok	Ok	Preferred
030		**Slot 1:**									
030	A	Not used	No	No	No	No	No	No	No	Ok	
030	B	4x universal U,I,TC,RTD, pulse-/frequency input	Yes	Yes	Ok	Ok	Ok	Ok	Ok	OK	required
030	C	4x HART/4...20mA input, HART transparency	No	No	Ok	Ok	Ok	Ok	Ok	Ok	
040		**Slot 2:**									
040	A	Not used	Ok	Ok	Ok	Ok	Ok	Ok	Ok	Ok	
040	B	4x universal U,I,TC,RTD, pulse-/frequency input	Ok	Ok	Ok	Ok	Ok	Ok	Ok	Ok	if needed
040	C	4x HART/4...20mA input, HART transparency	No	No	Ok	Ok	Ok	Ok	Ok	Ok	
050		**Slot 3:**									
050	A	Not used	Ok	Ok	Ok	Ok	Ok	Ok	Ok	Ok	
050	B	4x universal U,I,TC,RTD, pulse-/frequency input	Ok	Ok	Ok	Ok	Ok	Ok	Ok	Ok	if needed
050	C	4x HART/4...20mA input, HART transparency	No	No	Ok	Ok	Ok	Ok	Ok	Ok	
060		**Slot 4:**									
060	A	Not used	Ok	Ok	Ok	Ok	Ok	Ok	Ok	Ok	
060	B	4x universal U,I,TC,RTD, pulse-/frequency input	Ok	Ok	Ok	Ok	Ok	Ok	Ok	Ok	if needed
060	C	4x HART/4...20mA input, HART transparency	No	No	Ok	Ok	Ok	Ok	Ok	Ok	
070		**Slot 5:**									
070	A	Not used	Ok	Ok	Ok	Ok	Ok	Ok	Ok	Ok	
070	B	4x universal U,I,TC,RTD, pulse-/frequency input	Ok	Ok	Ok	Ok	Ok	Ok	Ok	Ok	
070	C	4x HART/4...20mA input, HART transparency	No	No	Ok	Ok	Ok	Ok	Ok	Ok	
070	D	Add. 8x digital input, 6x relay, 2x analog output	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Ok	Preferred
080		**Front Bezel:**									
080	A	Zink diecast, powder-coated, light grey	No	No	No	No	No	No	No	Ok	
080	B	Stainless steel, touchscreen,	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Ok	
080	C	DIN rail housing, no display	No	No	No	No	No	No	No	Ok	no annoation function at recorder
090		**Communication Master Functionality:**									
090	1	Not selected	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Ok	
090	2	Modbus RTU/TCP, Master	No	No	Ok	Ok	Ok	Ok	Ok	Ok	
100		**Communication Slave Functionality:**									
100	A	Not selected	Ok	Ok	Ok	Ok	Ok	Ok	Ok	Ok	
100	D	PROFINET, IO-Device	Ok	Ok	Ok	Ok	Ok	Ok	Ok	Ok	write function disabled when sealed
100	E	EtherNet/IP Server	Ok	Ok	Ok	Ok	Ok	Ok	Ok	Ok	write function disabled when sealed
110		**Application Package:**									
110	1	Not selected	No	No	No	No	No	No	No	Ok	
110	2	Mathematic	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Ok	required
110	3	Telealarm + mathematic	No	No	Yes	Yes	Yes	Yes	Yes	Ok	
500		**Operating Language Display:**									
550		**Calibration:**									
560		**Housing:**									
560	GA	Terminal cover, Display housing	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Ok	
570		**Service:**									
570	H8	Customized pre-configured	No	No	No	No	No	No	No	Ok	programming support from E+H required
570	H9	Special version, TSP-no. PMO Firmware	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Ok	
600		**Licence Package FDM Software MS20:**									
600	MA	Professional 1x workplace licence	No	No	No	No	No	No	No	Ok	Must MS21 server version of FDM
610		**Accessory mounted:**									
610	N1	SD card industrial grade, 1GB	No	No	No	No	No	No	No	Ok	included with SS touchscreen version
895		**Marking:**									

	Yes	order option mandatory for PMO applications				
	Ok	order option allowed for PMO applications				
			PMO	PMO		
Feature	TM311	Description	HTST	UHT/ESL	Aseptic	Comment
10		**Approval:**				
10	AA	Non-hazardous area	ok	ok	ok	
10	CA	CSA C/US General Purpose	yes	yes	yes	Preferred
20		**Output:**				
20	A	Pt100, 4-wire class A (IEC 60751)	yes	yes	yes	Preferred
20	B	IO-Link/4-20mA, variable measuring range, as specified	ok	ok	ok	must wire for 4-20mA
20	C	IO-Link/4-20mA, 0...+150oC	ok	ok	ok	must wire for 4-20mA
30		**Design; Diameter Insert:**				
30	0	W/o thermowell, direct contact; 6mm	yes	yes	yes	Preferred
40		**Material Wetted Parts:**				
40	B	316L	yes	yes	yes	Preferred
50		**Process Connection:**				
50	C2	Tri-Clamp, DN18 (0.75"), form B	yes	yes	yes	
50	D1	Clamp ISO2852, DN12 - 21.3, form B	yes	yes	yes	
50	D2	Clamp > NA Connect ISO2852, DN25 - 38 (1-1.5"), form B	yes	yes	yes	Preferred
50	D3	Clamp > NA Connect ISO2852, DN40 - 51 (2"), form B	yes	yes	yes	Preferred
60		**Surface Wetted Parts:**				
60	A	Not needed (installation in existing thermowell)				
60	B	Ra<=0.76um/30uinch	yes	yes	yes	Preferred
70		**Sensor Type; Measuring Range:**				
70	B	iTHERM TipSens; -50...+200oC	yes	yes	yes	Preferred
80		**Immersion Length U:**				
80	B2	20 mm	ok	ok	ok	
80	B4	30 mm	ok	ok	ok	
80	X1	..... mm (=<300)	ok	ok	ok	
80	X5	..... inch (=<11.5)	yes	yes	yes	Preferred typical 5.5"
90		**Thermowell Connection:**				
90	A	Not needed, no thermowell, direct contact	yes	yes	yes	preferred
100		**Neck Length E:**				
100	1	Not needed	ok	ok	ok	
100	2	50 mm (1.97")	yes	yes	yes	preferred
520		**>>Cable-Set:**				
570		**>>Service:**				
580		**>>Test, Certificate, Declaration:**				
590		**>>Additional Approval:**				
590	LB	3-A	yes	yes	yes	preferred
600		**>>Additional Option:**				
630		**>Calibration:**				
640		**>Calibration Points >=0oC:**				
650		**>Calibration Points <=0oC:**				
650	UA	0oC + 1 point -20...-1oC variable, as specified	ok	ok	ok	
650	UB	0oC + 2 points -20...-1oC variable, as specified	ok	ok	ok	
650	U9	Special version, TSP-no. to be spec.	ok	ok	ok	
850		**Firm Ware rev.**				
895		**Marking**				

	Yes	**order option mandatory for PMO applications**				
	Ok	**order option allowed for PMO applications**				
	No	**order option not allowed for PMO applications**				
			PMO	PMO		
Feature	**PMP43**	**Description**	**HTST**	**UHT/ESL**	**Aseptic**	**Comment**
010		**Approval:**				
010	CA	CSA C/US General Purpose	OK	OK	OK	Preferred
020		**Output:**				
020	BA	2-wire 4-20mA HART	**Ok**	**Ok**	Ok	Preferred
020	KA	4-20mA/IO-Link	Ok	Ok	**Ok**	
030		**Display; Operation:**				
030	G	Color display w/o touch control	Ok	Ok	Ok	Preferred
030	H	Color display w/o touch control +Bluetooth	Ok	Ok	Ok	BT turned off after set-up. Seal must be broken to re-activate.
040		**Housing; Material:**				
040	F	Compact; 316L	Yes	Yes	Yes	
050		**Electrical Connection:**				
050	N	Plug M12, IP66/68/69 NEMA Type 4X/6P	Yes	Yes	Yes	
055		**Pressure Type:**				
055	6	Gauge	Yes	Yes	Yes	
060		**Application:**				
060	B	Process temperature max 130oC/266oF,150oC/302oF max 1h	Yes	No	No	
060	C	Process temperature max 150oC/302oF	Ok	No	No	
060	D	Process temperature max 200oC/392oF	Ok	Yes	Yes	
075		**Sensor Range:**				
075	3M	4bar/400kPa/60psi	Ok	Ok	Ok	
075	3P	10bar/1MPa/150psi	Ok	Ok	Ok	
075	3R	25bar/2.5MPa/375psi	Ok	Ok	Ok	Preferred
080		**Surface Refinement:**				
080	A	Standard Ra<1.5µm/59uin	Yes	Yes	Yes	
080	Z	Not applicable				
090		**Calibration; Unit:**				
090	F	Sensor range; psi	Ok	Ok	Ok	
090	J	Customized linear; see additional spec.	Ok	Ok	Ok	Preferred factory pre-set range in psi
090	9	Special version, TSP-no. to be spec.				
105		**Process Connection, Sealing Surface:**				
105	TA	Clamp/Tri-Clamp	OK	OK	OK	Preferred
105	99	Special version, TSP-no. to be spec.				
110		**Process Connection:**				
110	3BJ	Tri-Clamp > (1"), 316L, DIN32676 DN40 NA Connect ISO2852 DN25	Ok	Ok	Ok	Preferred
110	3CJ	Tri-Clamp > (1-1/2"), 316L, DIN32676 DN40 NA Connect ISO2852 DN25-38	Ok	Ok	Ok	Preferred
110	3EJ	Tri-Clamp > (2"), 316L, DIN32676 DN50 NA Connect ISO2852 DN40-51	Ok	Ok	Ok	Preferred
110	3FJ	Tri-Clamp > (3"), 316L NA Connect ISO2852 DN76.1	Ok	Ok	Ok	Preferred
110	3JJ	Tri-Clamp > (2-1/2"), 316LNA Connect ISO2852 DN63.5	Ok	Ok	Ok	Preferred
170		**Membrane Material:**				
170	A	316L	Ok	Ok	Ok	
180		**Fill Fluid:**				
180	3	Synthetic oil, FDA	Yes	No	No	Tied to Temp rating
180	4	Vegetable oil, FDA	Ok	Yes	Yes	Tied to Temp rating
500		**>Operation Language Display:**				
540		**>>Application Package:**				
540	EH	Heartbeat Verification + Monitoring	No	No	Ok	
545		**>Reference Accuracy:**				
550		**>Calibration:**				
570		**>>Service:**				
580		**>>Test, Certificate, Declaration:**				
590		**>>Additional Approval:**				
590	LB	3-A, declaration	Yes	Yes	Yes	Required for all dairy applications
590	LC	EHEDG, declaration	Ok	Ok	Ok	
590	LS	CRN	Ok	Ok	Ok	
620		**>>Accessory Enclosed:**				
895		**>>Marking:**				

Accessories

- RFID access/log on to recorder
  Memograph M RSG45 is compatible with RFIdeas and other employee RFID badge readers and can be used with most employee badge types, including MFT and single sign on.
  Part# RDR-805W1BKU + Panel Mount IP67 Kit: KT-IP67

- M12 locks to accommodate regulatory tamper seals on instruments with M12 electrical connection
  Part #TTSP-AT1642

Supplementary documents

For additional information please refer to the following supplementary documents:

- User manual: *Memograph M RSG45 (PMO_Memograph_M_RSG45_Manual SD03224B09EN012500) for PMO applications (M-b-385 Endress Hauser Memograph M RSG485)*
- *FDM and Memograph M RSG45 operator-administrator instructions*
- *FDM technical information* TI01022R/09/EN/09.21
- *FDM MS21 installation and set-up instructions* (English, see pg. 27) KA00466C07A2
- User manual: *FDM MS20/21 (Field Device Manager) software* BA00288R/09/EN/12.21
- *7-day test form for initial installation per PMO*
- *PMO regulatory systems sign off form*
- Whitepaper: *Memograph M RSG45 and FDM FDA 21 CFR, part 11* (WP01028L)

www.addresses.endress.com

Endress+Hauser

People for Process Automation