# Appendix I **Memograph M RSG45**

Pasteurization Equipment and Controls – tests for Memograph M RSG45 paperless recorder





### Appendix I

# Pasteurization Equipment and Controls – tests for Memograph M RSG45 paperless recorder

Prepared by: Endress+Hauser

This document is designed to provide greater detail with respect to performing state regulatory testing as required by Appendix I of the Pasteurized Milk Ordinance. Procedures are applicable for all HTST (High Temperature Short Time), UHT (Ultra High Temperature) and ESL (Extended Shelf Life) systems. Note that guidance for Aseptic Pasteurizers falls under FDA CFR21, part 113.

Note: To make program changes related to the test, the unit will need to be in program mode (jumper terminal 1 open).

Initial compliant program verification (for Memograph M RSG45-specific setup requirements, see page 11 onward in this document.):

- 1. Lock jumper in place (digital terminal #1)
- 2. Administrator(s) and main users set up per 21CFR, part 11
- 3. Input wiring per manual section 1.6
- 4. Verify programming per document "PMO STLR\_SFLR program place in service review" as applicable to STLR, SFLR, DP... application

#### **Test 1 – Indicating Thermometers – Temperature Accuracy**

Not Applicable

### **Test 2 – Temperature Recording and Recorder-Controller Thermometers** – **Temperature Accuracy**

Not Applicable

**Application:** To all temperature recording and recorder-controller thermometers used to record milk and/or milk product temperatures during pasteurization and/or ultrapasteurization, except those which are electronic or computer controlled.

#### Test 3 – Temperature Recording and Recorder-Controller Thermometers - Time Accuracy

**Criteria:** The recorded time of pasteurization or ultra-pasteurization shall not exceed the true elapsed time.

**Method:** A comparison of the recorded time over a period of not less than thirty (30) minutes with an accurate time-measuring device.

- 1. Memograph M RSG45 will always show the time and date due to its real-time clock.
- 2. Check and verify the correct time and accuracy of the clock prior to proceeding with further testing
- 3. Verify that Daylight Saving Time (DST) of the clock is set up for local conditions
  - a. Automatic adjustment recommended (In this mode, spring and fall changes will be done automatically)
  - b. While in program mode, select the MENU softkey
  - c. Select EXPERT
  - d. Select SYSTEM
  - e. Select DATE/TIME SETUP
  - f. Select NT/ST CHANGEOVER = AUTOMATIC

### Process for completing test:

- 1. Secure known accurate stopwatch
- 2. Select the "Operation" menu from the front display
- 3. Using the "Store Text" function, select the "Test 3 Start" pre-defined message
  - a. Note it is helpful if this message is entered when crossing an hour mark or portion of an hour such as, "10 minutes or 30 minutes past the hour"
  - b. START stopwatch at same time to begin test
- 4. Using the "Event" key on the front display, pull up "Event" log to show exact time of entry add 30 min (minimum) to this value to determine stopping point
- 5. Upon passing of at least 30 minutes, again go to "Store Text" function
  - a. Select the "Test 3 End" pre-defined message
  - b. Hit "STOP" button on stopwatch
- 6. Using the "Event" key on the front display, pull up "Event" log to show exact time of entry
  - a. Calculate the elapsed time from "Test 3 Start" to "Test 3 End" entries
  - b. Compare to time on stopwatch

### **Test 4 –** Temperature Recording and Recorder-Controller Thermometers – Checked Against Indicating Thermometer

**Criteria**: The temperature recording thermometer and recorder-controller thermometer shall not read higher than the indicating or airspace thermometer, which were previously tested against a known accurate test thermometer.

**Method**: This test requires only that the reading of the temperature recording thermometer recorder-controller thermometer or airspace recording thermometer be compared with the indicating thermometer at a time when both are exposed to a stabilized temperature at or above the minimum legal pasteurization temperature.

Immediately enter the results, the time at which this comparison was made and initial the recording chart. This may be accomplished by inscribing a line intersecting the recorded temperature arc at the pen location or any other method acceptable to the regulatory agency.

- 1. Inspector can manually enter notation into Memograph M RSG45 indicating this test was done
  - a. This note will be time stamped, and the user administration will show that the inspector was logged into the unit
  - b. Select the "Operation" menu from the front display
  - c. Using the "Store Text" function, select the "New Text" pre-defined message
  - d. Store indicating = "XXX.X" where "XXX.X" is the indicating thermometer value
  - e. From the front display, select the "Events" softkey
  - f. Here, you can view the event entries showing the logged value

**Action:** If the temperature recording thermometer or recorder-controller thermometer reads higher than the indicating thermometer, the pen or temperature adjusting mechanism shall be adjusted by milk plant personnel to agree with the indicating thermometer.

If an adjustment is needed, an offset can be introduced to the input section of the temperature recording device.

### Test 5 - FDD - Proper Assembly and Function

Not Applicable

#### **Test 6 – Batch (Vat) Pasteurization Leak-Protector Outlet Valve**

Not Applicable

### **Test 7 –** Indicating Thermometers Located Within HTST Pasteurization Systems – Thermometric Response

Not Applicable

#### Test 8 - Temperature Recorder-Controller Thermometers - Thermometric Response

To test the recording thermometric response time, the hot product digital display value shall be used instead of the graph.

Note: Cut in temperature = set point + Hysteresis. (Example: 178+1.5=179.5)

**Method:** Measure the time interval between the instant when the temperature recorder-controller thermometer reads  $7^{\circ}$ C ( $12^{\circ}$ F) below the cut-in temperature and the moment of cut-in by the temperature recorder-controller. This time interval measurement is made when the temperature recorder-controller sensing element is immersed in a rapidly agitated media bath maintained at  $4^{\circ}$ C ( $7^{\circ}$ F) above the cut-in temperature.

**Action:** If the response time exceeds five (5) seconds, the temperature recorder-controller shall be repaired or replaced by milk plant personnel.

#### **Test 9 – Regenerator Pressure Controls**

9.1 Differential Pressure Controller (Note: "Differential Pressure" function is currently not supported under M-b xx)

#### 9.1.1 Calibration of the Differential Pressure Controller Sensing Elements

#### Procedure:

1. Loosen the sanitary pipeline connections to both differential pressure controller pressure sensing elements and wait for any liquid to drain through the loose sanitary pipeline connections. Both pointers and digital displays shall be within 3.5 kPa (0.5 psi) of 0 kPa (0 psi). If not, adjust the pointer(s) or the digital display(s) to read 0 kPa (0 psi).

If an adjustment is needed, an offset can be introduced to the input section of the pressuresensing elements

**Action:** If the differential pressure controller fails to respond as indicated above, an immediate check of the differential pressure controller is required by milk plant personnel to correct the cause of the failure.

### 9.1.2 HTST - Interwiring of the Differential Pressure Controller with the Booster Pump

There are no differences for the testing procedure between the current differential pressure controller and Memograph M RSG45

## 9.1.3 HTST – Interwiring of the Differential Pressure Controller with the FDD in an HHST Continuous-Flow Pasteurization System

There are no differences seen here on the testing procedure between the current differential pressure controller and Memograph M RSG45  $\,$ 

### **Test 10** – Milk or Milk Product-Flow Controls and the Milk or Milk Product Temperature at Cut-In and Cut-Out

#### 10.1 HTST Pasteurization Systems

Observe the indicating thermometer reading at the moment forward flow begins, i.e., the FDD moves. Observe that the recorder-controller event pen reading is synchronized with the recording pen on the same reference arc as on the recording chart.

Immediately record and identify on the recording chart the observed indicating thermometer temperature reading at cut-in and initial the recording chart. This may be accomplished by inscribing a line intersecting the recorded temperature arc at the pen location or any other method acceptable to the regulatory agency.

- 1. All functions on the recorder are "Digital"
  - a. Recording pen is shown as line on chart and as digital value
  - b. FDD status is indicated as "Divert" and "Forward" in text field as well as an event pen at the bottom of the graph (full bar or "1" = forward)
- 2. In lieu of inscribing a line, the inspector will add an annotation to denote the indicating thermometer temperature reading. This will be valid for both the cut-in and cut-out temperatures
  - a. Raise or lower process temperature accordingly for cut-in or cut-out
  - Note the indicating thermometer temperature at the time system moves to Cut-in or cut-out (depending on test being performed)
  - c. Select the "Operation" menu from the front display
  - d. Using the "Store Text" function, select the "New Text" pre-defined message
  - e. Store "Cut-In (Out) XXX.X" where "XXX.X" is the indicating thermometer value
  - f. Complete for both cut-in and cut-out
  - q. From the front display, select the "Events" softkey
  - h. Here, you can view the "Event" entries showing the logged cut-in and cut-out values, along with the setpoint values that were crossed
  - i. Remember that cut-in = setpoint + hysteresis (same as determined during Test 8), and cut-out = setpoint

**Action:** If the cut-in and/or cut-out indicating thermometer reading is below the minimum legal pasteurization temperature, the cut-in and/or cut-out setting(s) shall be adjusted by milk plant personnel.

- 1. This is accomplished by changing the limit values in te Memograph M RSG45
  - a. Raising or lowering the limit values will adjust the point at which the unit moves to "Forward" or "Divert"
  - b. Note: This can only be changed by the administrator when the lock is removed.

#### 10.2 Pasteurization Systems Using Indirect Heating

There are no differences seen here regarding the testing procedure between the current recorder-controller and Memograph M RSG45.

Verify with regulatory

#### 10.3 Pasteurization Systems Using Direct Heating

There are no differences seen here regarding the testing procedure between the current recorder-controller and the Memograph M RSG45.

Verify with regulatory

### **Test 11** – Continuous-Flow Pasteurization System Holding Tubes – Pasteurization Holding Time

#### 11.1 HTST Pasteurization Systems

Not Applicable

### 11.2A Continuous-Flow Pasteurization Systems Utilizing a Magnetic Flowmeter-Based Timing System – Pasteurization Holding Time

Adjust the set point on the flow recorder-controller to a flowrate estimated to yield an acceptable pasteurization holding time.

- 1. The loss of signal/high flow set points can be changed under the "Limit" menu
  - a. From front display select "Operation" softkey
  - b. From "Operation" menu, select "Limits"
  - c. Here, you are able to modify set point 2 (high flow point) as needed. Make sure to document original value and reset after test

Channel/value	: Product_Flow
Type	: Inband
Identifier	:Flow alarm
Set point	: 8 GPM
Set point 2	: 200 GPM
Hysteresis (abs.)	: 0.5 GPM
Time delay	:0 s
Switches	:Relay 3
LV messages	: Do not acknowledge

### 11.2B Continuous-Flow Pasteurization Systems Utilizing a Magnetic Flowmeter-Based Timing System – Holding Tubes and High Flow Alarm

Slowly raise the flow rate of the pasteurization system until the following occurs: a. The frequency pen(s) on the STLR and the flow rate recorder-controller(s) indicate that the FDD is in the diverted-flow position.

- 1. Flow recording pen is shown as a line on the chart and as a digital value
  - a. The FDD status is indicated as "Divert" and "Forward" in the text field as well as an event pen at bottom of graph (full bar or "1" = forward)
  - b. Flow status is indicated as "Good" vs "Bad" ("Good" = within limits)
  - c. In addition, a flow event pen is located above the FDD event pen (full bar or "1" = good)

### 11.2C Continuous-Flow Pasteurization Systems Utilizing a Magnetic Flowmeter-Based Timing System – Holding Tubes and Low Flow/Loss-Of-Signal Alarm

Disrupt the power to the magnetic flowmeter to activate the loss-of-signal alarm or decrease the flow through the flowmeter to a flow rate below the low flow alarm setpoint. Observe that the FDD assumes the diverted-flow position and that the frequency pen(s) on the STLR and the flow rate recorder-controller(s) assumed the diverted-flow position.

- 1. Simulate by setting "Flow Rate" to a value below the "Loss of Signal" setpoint
  - a. With flow moving below the "Loss of Signal" setpoint value, the FDD will move to diverted flow

2. Disconnecting the signal wire for the flow signal will simulate a signal loss of the magnetic flowmeter, immediately showing an error on Memograph M RSG45.

a. The recorded flow will go to 0 and the set point will not be met. This will cause the FDD to move to "Diverted Flow"

If the FDD does not divert or the frequency pens do not assume the diverted-flow position, milk plant personnel shall make an adjustment to the low flow/loss-of-signal alarm or a modification to the FDD, the STLR or flow rate recorder-controller as required.

3. When the connection is lost to the magnetic flowmeter, Memograph M RSG45 will always default to the failsafe diverted position.

### 11.2D Continuous-Flow Pasteurization Systems Utilizing a Magnetic Flowmeter-Based Timing System – Holding Tubes and Flow Rate Cut-In and Cut-Out

Using the flow rate recorder-controller, slowly increase the flow rate until the frequency pen on the flow rate recorder-controller indicates a flow-diversion because the high flow alarm set point had been exceeded. The FDD shall assume the diverted-flow position. Observe the flow rate reading from the flow rate recorder-controller the instant forward-flow cut-out occurs, as indicated by the flow rate recorder-controller's frequency pen.

With the pasteurization system operating on water, above the minimum legal pasteurization temperature and with the FDD in the diverted-flow position due to exceeding the high flow alarm set point, slowly decrease the flow rate until the frequency pen on the flow rate recorder-controller indicates the start of the FDD's forward-flow movement, which indicates the flow rate cut-in point. Because of the time delay described in Test 11.2E, the FDD will not move immediately to the forward-flow position. Observe the flow rate reading from the flow rate recorder-controller the instant flow rate cut-in occurs, as indicated by the flow rate recorder-controller's frequency pen.

- 1. Flow recording pen is shown as line on chart and as digital value
  - a. The FDD status is indicated as "Divert" and "Forwar" in text field as well as an event pen at bottom of graph (full bar or "1" = forward).
  - b. Flow status is indicated as "Good" vs "Bad" ("Good" =within limits).
  - c. In addition, a flow event pen is located above the FDD event pen. (full bar or "1" = Good)

### 11.2E Continuous-Flow Pasteurization Systems Utilizing a Magnetic Flowmeter-Based Timing System – Holding Tubes and Time Delay

Using the flow rate recorder-controller, slowly increase the flow rate until the frequency pen on the flow rate recorder-controller indicates a flow-diversion and the FDD moves to the diverted-flow position. There shall not be any time delay between the movements of the flow rate recorder-controller's frequency pen and the FDD.

Start the accurate time measuring device the instant the flow rate recorder-controller's frequency pen indicates flow rate cut-in.

Not a function of Memograph M RSG45, must be performed with stand-alone time delay relay.

### 11.2F Continuous-Flow Pasteurization Systems Utilizing a Magnetic Flowmeter-Based Timing System – High Flow Alarm Response Time

- 2. Identify the high flow alarm set point on the flow rate recorder-controller chart. This may be accomplished by inscribing a line intersecting the recorded flow arc at the pen location or any other method acceptable to the regulatory agency.
- 3. Increase the pasteurization system flow rate as rapidly as practical to a point above the high flow alarm set point.
- 4. Start the accurate time measuring device when the flow rate recorder-controller's recording pen exceeds the high flow alarm set point.
- 1. The high flow alarm set point can be seen under the "Limits" menu described above.
  - a. The flow high alarm can be observed by selecting the Operation softkey from the front display
  - b. From the "Operation" menu, select "Limits"
  - c. Here you are able to see the set point 2 (high flow)

Channel/value	: Product_Flow
Туре	: Inband
Identifier	: Flow alarm
Set point	: 8 GPM
Set point 2	: 200 GPM
Hysteresis (abs.)	: 0.5 GPM
Time delay	:0 s
Switches	:Relay 3
LV messages	: Do not acknowledge

- 2. With the stop watch ready, quickly increase the flow rate to a value expected to go beyond High Flow Setpoint
- 3. Press "START" on the stopwatch as soon as the "FLOW RATE" label on the flow rate display of the recorder changes to red and the flow status goes from "Good" to "Bad"
- 4. "STOP" the stopwatch as soon as the FDD visibly moves to divert resulting time should be less than one second

### 11.3 Calculated Pasteurization Holding Time for HHST Pasteurization Systems Using Indirect Heating

Not Applicable

### 11.4 Calculated Pasteurization Holding Time for HHST Pasteurization Systems Using Indirect Heating

Not Applicable

# 11.5 HHST Pasteurization Systems Holding Time Using Direct Steam Infusion Heating With a Steam Pressure Relief Pop-Off Valve and a Vacuum Chamber Orifice in Place of a Timing Pump

Not Applicable

### Test 12 - Thermal-Limit-Controller for Control - Sequence Logic

### 12.1 Pasteurization - Indirect Heating

There are no differences seen here on the testing procedure between the current differential pressure controller and Memograph M RSG45.

### 12.2 Pasteurization - Direct Heating

There are no differences seen here on the testing procedure between the current differential pressure controller and Memograph M RSG45.

### Test 13 – Setting of Control Switches for Milk and/or Milk Product Pressure in the Holding Tube

Not Applicable

### Test 14 - Setting the Control for the Differential Pressure Controller Across the Steam Injector

Not Applicable

#### Test 15 - Electro Magnetic Interference From Hand-Held Communication Devices

As documented in Pasteurized Milk Ordinance

### Operating instructions Memograph M RSG45

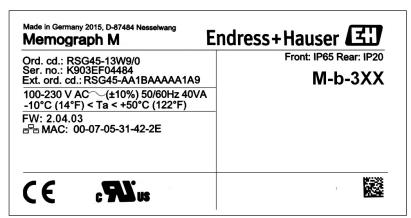
#### 1.2. Software revision

The firmware revision for PMO applications is ENX200A 2.06.00 (last 2 digits bugfix index do not need to be 00). Memograph M RSG45 device including PMO specific firmware is ordered via option 570 Service "9 special version", TSP no. 71631208.

For questions on ordering or any support regarding PMO applications please contact: Endress+Hasuer USA 2350 Endress Place Greenwood, IN 46143 1-888-363-7377

#### 1.3. Identification of device

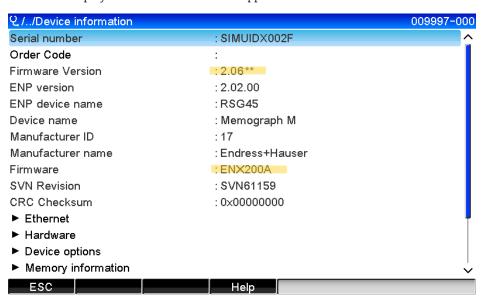
All device information like serial number, order code and firmware version are printed on the type plate of Memograph M RSG45. The device can be uniquely identified, and the ordering options can be compared with the options allowed for PMO applications. The M- b Memoranda index is printed on the type plate\*.

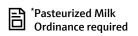


All device information can be displayed during operation by selecting:

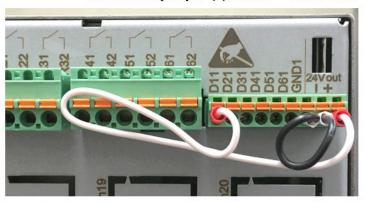
### Menu -> Diagnostics -> Device Information

The screen display with all information will appear as shown below.





### Ground (-) bridge -> black wire Protection jumper (+) to D11 -> white wire



\*Pasteurized Milk Ordinance required

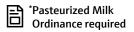
**Figure 6:** Lock out jumper - connect jumper between terminal - and GND and + this jumper must be in place during operations and disconnected to allow program changes\*

### 2.1.1 Activation of FDA user administration

\*Pasteurized Milk Ordinance required Select the setting for **FDA 21 CFR Part 11** administration under\*: **Menu -> Setup -> Advanced setup -> System -> Security -> Protected by** 



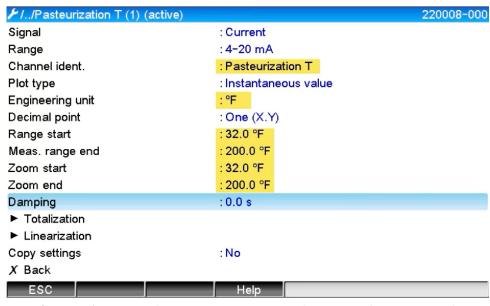
### 2.2.1 Example set up for a temperature measurement value



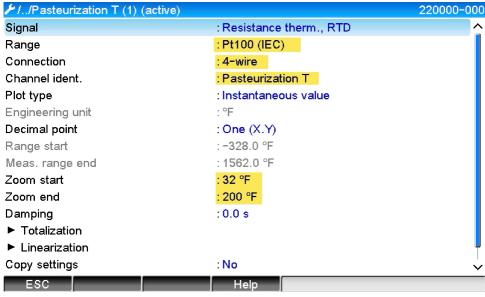
Values highlighted in yellow will or may need to be adjusted based on local application needs. To record a measured temperature value, please proceed as follows\*:

#### Menu -> Setup -> Advanced setup -> Inputs -> Universal inputs -> Add input

Select physical input by channel #1, set up channel name (e.g. Pasteurization T), define measurement and display range, etc. For all details, please refer to Memograph M RSG45 operating manual. Temperature sensors for PMO applications can be analog 4-20mA sensors or 3/4-wire RTD sensors. See example configurations below.



Example: setup of 4-20mA analog temperature sensor; note: damping must be set to 0 seconds



**Example:** setup of 4-wire RTD analog temperature sensor; note: damping must be set to 0 seconds

### 2.2.3 Limit switches (divert set-point) for temperature measurement

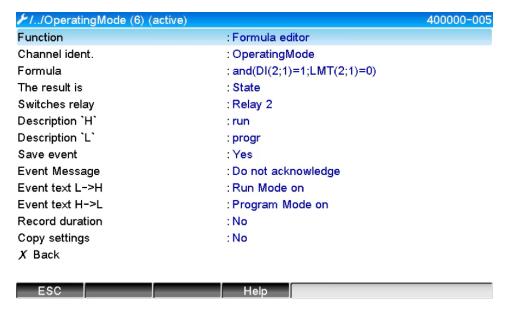
\*Pasteurized Milk Ordinance required Monitoring the process temperature is the most important aspect in heat treatment process applications. The measured value can be monitored with limit values. Limit value violations are logged in the audit trail and displayed in the recording. Setting up a divert set-point temperature for a measuring channel\*:

Menu -> Setup -> Advanced setup -> Application -> Limits -> Add limit value

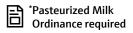
	* *	
		450000-000
Channel/value	: Pasteurization T	^
Туре	: Lower set point	
Identifier	: Set Point Temp	
Set point	: 168.0 °F	
Hysteresis (abs.)	: 1.5 °F	
Time delay	:0 s	
Switches	: Not used	
LV messages	: Do not acknowledge	
Save event	:Yes	
Event text LV on	:	
Event text LV off	:	
Record duration of LV on	: No	
Save cycle	: Normal	
Draw help line	:Yes	
Copy settings	: No	~
ESC	Help	

#### Programming vs operating mode

\*Pasteurized Milk Ordinance required To switch relay #2 indicating the divert set-point temperature has been met to the public health controller, the following two math channels logic need to be set to ensure that forward flow is not possible in unlocked (programming mode)\*.



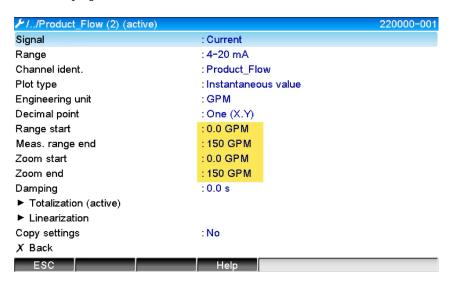
#### 2.3.1 Configuration of flow monitoring



To record and monitor the flow value, please proceed as follows\*:

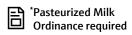
**Menu -> Setup -> Advanced setup -> Inputs -> Universal inputs -> Add input**Select physical input channel 2, set up channel name (e.g. Flow), select unit GPM and measurement range 0 to XXX GPM. The maximum value XXX for the flow corresponds to the 20mA signal which equals to the calibrated signal of the flow sensor. In the example for the screenshots, a maximum flow rate of 150 GPM was chosen.

Note: Damping shall be set to 0.0 seconds

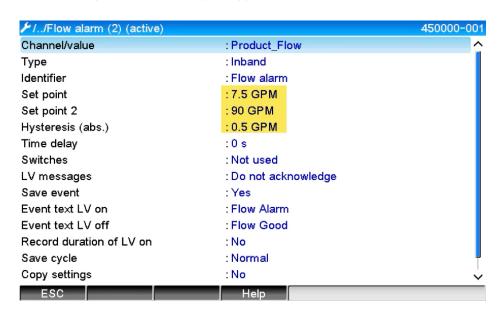


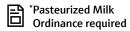
The measured flow value is recorded and the trigger limit switch for high flow alarm and low flow (loss of signal). These limit value violations are logged in the audit trail and displayed in the recording.

#### 2.3.2 Setting up the alarm limit(s) for flow (loss of signal and high flow)



Setting up the limit switch for loss of flow and high flow, please proceed as follow\*: **Menu -> Setup -> Advanced setup -> Application -> Limits -> Add limit value** 

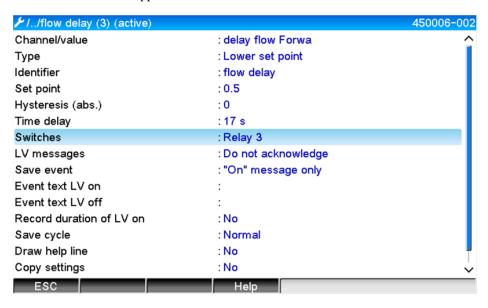




Setting up the forward flow delay for flow divert relay, please proceed as follows\*:

### Menu -> Setup -> Advanced setup -> Application -> Limits -> Add limit value

Relay 3 – assigned flow alarm/set point. A typical 17-second delay is needed to clear the hold tube after a flow alarm. This might differ depending on application and product. Time delay value must be set based on actual application need.



\*Pasteurized Milk Ordinance required For hold tube delay to function, a math channel #8 needs to be created—see example below\*

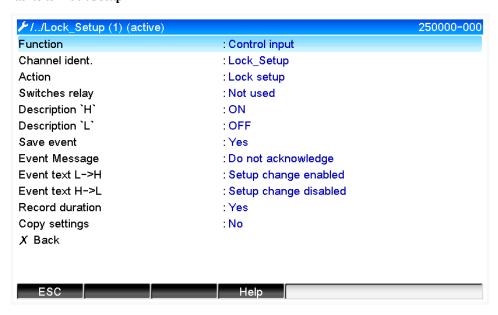
Menu -> Setup -> Advanced setup -> Application -> Maths-> Math 8 (delay flow forwa)

		400000-007
Function	: Formula editor	
Channel ident.	: delay flow Forwa	
Formula	: LMT(2;2)	
The result is	: Instantaneous value	
Plot type	: Instantaneous value	
Engineering unit	:	
Decimal point	: None	
Zoom start	:0	
Zoom end	:1	
► Totalization		
Copy settings	: No	
X Back		
ESC	Help	

### 2.4 Setup protection

\*Pasteurized Milk Ordinance required For PMO applications, the changing of the setup (all parameters) need to be secured against accidental or intentional modification by configurating digital input #1 as a "setup lock." Activation of the setup lock in Memograph M RSG45 settings\*:

Menu -> Setup -> Advanced setup -> Inputs -> Digital inputs -> Add input-add input #1 name it "Lock Setup"

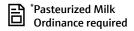


To ensure that relay 2 cannot be activated (forward flow) in programming mode the following math function must be programmed:

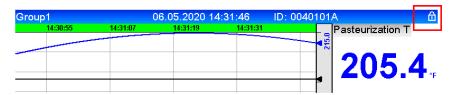
Menu -> Setup -> Advanced setup -> Application -> Maths-> Math 6 (operating mode)

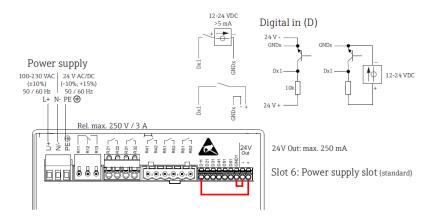


The digital input #1 (D11) is connected to +24V/DC by a jumper (wire bridge) according to the wiring diagram below for digital input D11.

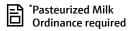


During operation, the setup lock is indicated on the top right corner of the display\*.

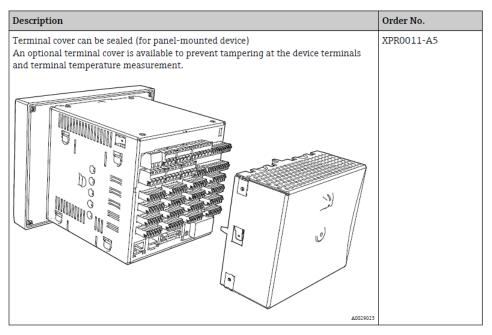




### 2.5 Terminal cover

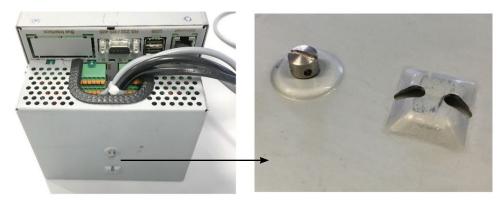


After commissioning, the device and wiring and all setup settings are finished, the hardware protection jumper (see above) is connected and the complete terminal block of the device are covered by Memograph M RSG45 terminal cover for panel and can be sealed with a regulatory seal like shown in the picture below\*.



RSG45 terminal cover

### Terminal cover mounted on Memograph M RSG45



Terminal cover on Memograph M RSG45 zinc diecast version

Fixing screw with hole for regulatory seals



